

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

IN RE: VALSARTAN PRODUCTS :
LIABILITY LITIGATION : DEPOSITION DESIGNATION
: HEARING VIA TEAMS

Mitchell H. Cohen Building & U.S. Courthouse
4th & Cooper Streets
Camden, New Jersey 08101
September 24, 2024
Commencing at 9:35 a.m.

B E F O R E: THOMAS I. VANASKIE (RET.)
SPECIAL MASTER

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24 Proceedings recorded by mechanical stenography; transcript produced by computer-aided transcription.

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28 **ALSO PRESENT:**

29
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1 (PROCEEDINGS held via Teams before SPECIAL MASTER
2 THOMAS I. VANASKIE at 9:35 a.m.)

3 SPECIAL MASTER VANASKIE: We're going to get started
4 on reviewing deposition excerpt designations and ruling on
5 objections.

6 We're going to get as far as we can today. We won't
7 get through everything, so you understand going in that I'm
8 not prepared to complete everything today. But we'll get as
9 far as we can, and then we have scheduled time later during
10 the week, and we'll resume then, if that's all right.

11 We'll proceed as I did with the ZHP -- the
12 designations of ZHP witnesses. I'll entertain brief argument
13 and make rulings.

14 It seems to me, and correct me if I'm wrong -- and I
15 will ask for guidance on this -- that I've got to go excerpt
16 by excerpt.

17 Does anybody disagree with that?

18 MR. STANOCH: Your Honor, David Stanoch for
19 plaintiffs.

20 I think that's generally correct, but I am hopeful
21 that once we get into some of these witnesses and you address
22 the larger subject matter or issue or document that's being
23 discussed, that may move along very similar subsequent
24 objections.

25 SPECIAL MASTER VANASKIE: That's what I'm hoping.

1 And I wanted to ask at the outset whether you all have met and
2 conferred with respect to each of the challenged designations.

3 MR. STANOCH: Your Honor, David Stanoch for
4 plaintiffs again.

5 Yes. I believe that's true for all of them for Teva
6 and Torrent. And what we've provided you are of the ones that
7 remain in dispute. There are a number of others which we
8 simply excised where we've reached agreement.

9 SPECIAL MASTER VANASKIE: All right.

10 Now, the first witness I wanted to take up is
11 Elisabeth Gray.

12 That seemed to be pretty straightforward. And I got,
13 as I noted earlier, some counter-designations today. And I
14 don't think we'll be addressing them, as they did -- were just
15 brought to me.

16 But let me -- I have the spreadsheet with the
17 objections, my tentative rulings, and let me pull up the
18 transcript itself. Okay. I'm going to do this. I only have
19 two screens, I don't have three screens. So I have the
20 transcript in front of me, and I have the spreadsheet on
21 another screen.

22 I don't have -- I won't be looking at you. You'll be
23 able to see me, of course. And we'll go -- as I said, I
24 intended to go excerpt by excerpt, at least at the outset.

25 So the first excerpt from the deposition of Elisabeth

1 Gray on February 26, 2021, the plaintiffs' affirmative
2 designation is at page 49, line 22, to page 50, line 9.

3 Then I have a counter-designation at page 51, line 5,
4 to page 53, line 1.

5 MS. LOCKARD: That's correct, Judge.

6 SPECIAL MASTER VANASKIE: Go ahead.

7 MS. LOCKARD: So Victoria Lockard for Teva. I think
8 the issue on a few of these, and you'll see throughout, is the
9 ongoing disagreement between the parties about the rule of
10 completeness.

11 And we actually briefed this in standalone briefing
12 as to how much of this completeness rule applies.

13 Plaintiffs' position has been almost essentially that
14 the only thing you can play in a completeness counter is just
15 to complete the sentence.

16 And that's not actually the law. Under Evidence
17 Rule 106, if a party introduces all or part of a writing or a
18 statement, including a deposition, the adverse party may
19 require the introduction at that time of any other part or any
20 other writing that in fairness ought to be considered.

21 And in our briefing, I won't go through all of it,
22 but we go through case law, including Supreme Court precedent
23 that specifically says that we are entitled to play more than
24 just the rest of the sentence, that we are entitled to play
25 additional testimony if it would provide an accurate

1 representation of the statement and avoid prejudice and
2 confusion. And so that's what we have endeavored to do.

3 And with Judge Bumb's ruling, she had said repeatedly
4 that the defendants will be allowed to play their clips from
5 the deposition at the same time as plaintiffs. She wants the
6 videos played just once.

7 So that's the preliminary ground on which we make
8 these completeness counters. And so you're going to hear from
9 plaintiffs that it introduces additional information not
10 within the underlying question.

11 But in fairness and under Judge Bumb's rulings, we
12 think we ought to be able to provide these counters to provide
13 context and clarity for the deponent's statement.

14 SPECIAL MASTER VANASKIE: All right.

15 David?

16 MR. STANOCH: Thank you, Your Honor. I'll be brief.

17 We disagree that Judge Bumb has issued any ruling
18 whatsoever on completeness. Your Honor addressed completeness
19 designations for hours on Friday with ZHP.

20 I think it's suffice to say that the purpose of
21 completeness is to address something that is specifically out
22 of context or misleading. It's not for defendants, or any
23 party, for that matter, to inject page upon page and line upon
24 line of additional testimony to dilute that which we are
25 allowed to designate from a party opponent admission.

1 And I'll just leave it at that, Your Honor.

2 SPECIAL MASTER VANASKIE: All right. Well, the first
3 three excerpts for which there are objections -- let me just
4 make sure -- dealt with this completeness question. And as I
5 said, we are at page 51, line 5, to page 53, line 1.

6 I am going to allow those counter-designations. The
7 counter-designation at page 51, lines 5, to page 53, line 1.

8 I also looked at the completeness question with
9 respect to the excerpt at page 76, lines 1 to 4, and the
10 counter and affirmative designation at page 103, lines 4 to
11 14, and page 106, lines 14 to 18.

12 And I think they all come in. So to the extent there
13 are objections, they're overruled. The testimony may come in.
14 That's the guidance I'll give you on that.

15 MR. STANOCH: Your Honor, plaintiffs understand your
16 ruling. I'm not going to argue every single time here on a
17 rule against us.

18 SPECIAL MASTER VANASKIE: Right.

19 MR. STANOCH: Obviously, I appreciate that to move
20 this along.

21 And obviously, to the extent after this we decide to
22 remove our designation in light of the completeness ruling,
23 that would take away both the designation and the completeness
24 designation. Teva may want to affirmatively designate it, but
25 that's a different issue.

1 SPECIAL MASTER VANASKIE: That's a different issue.

2 MR. STANOCH: I would only look at page 103, line 4,
3 question and answer, Your Honor.

4 SPECIAL MASTER VANASKIE: Let me get to it.

5 All right. I'm looking at it.

6 MR. STANOCH: You'll see here, the question is simply
7 about the exhibit itself that we're talking about. And then
8 she says, "there is not," but then goes on and on about what
9 the FDA may or may not do. She's speculating about what they
10 may have done.

11 We think that's not -- not appropriate completeness
12 and would not be, frankly, appropriate testimony for Teva to
13 elicit on their own direct.

14 SPECIAL MASTER VANASKIE: All right. Victoria?

15 MS. LOCKARD: Well, Your Honor, our position on this
16 is the question is asking this witness, well, in the
17 submission to FDA, did you include any mention of testing?
18 And the witness is saying there's not, but if the FDA wanted
19 additional testing, they could ask for it. And I think that's
20 fair for the jury to understand.

21 SPECIAL MASTER VANASKIE: Yeah. I agree. My
22 inclination was to allow the testimony, overrule the
23 objections. And I'll adhere to that determination.

24 All right. The next excerpt I have deals with the
25 question -- deals with testimony at page 110, line 15, to 111,

1 line 12.

2 MS. LOCKARD: So, Your Honor, if I may, so this is a
3 regulatory witness. She was a 30(b)(6) corporate rep. She
4 was designated to discuss communications between Teva and the
5 FDA.

6 What she's being asked about here is outside of the
7 scope of the 30(b)(6) notice topics. It's also outside of her
8 personal knowledge, in violation of Rule 602, which requires
9 the witness to have personal knowledge.

10 So she either has to be testifying within the scope
11 of the 30(b)(6) topic or she has to have personal knowledge.

12 She doesn't. She's not a quality testing person.
13 Teva has another witness, we'll discuss it on another date,
14 who was designated to talk about what testing Teva did. It's
15 Tony Binsol. And there's plenty of testimony about that
16 testing. Dan Barreto will also address that.

17 This witness is in the regulatory department. She
18 takes the information that's provided and she prepares the
19 submissions and submits them to FDA.

20 And so plaintiff is asking her, well, you know, you
21 don't know what testing was done, you don't know what testing
22 was done. And she's trying to explain in here, no, you know,
23 that's a quality function. And I think it's misleading
24 because it leads the jury to believe that testing wasn't done
25 when, in fact, it was. And that will be explained by other

1 witnesses.

2 So we drew a line here. So where she's asked
3 questions about, well, is there any reference of testing in
4 the submission to FDA, and she can say no, that's not in the
5 submission. But when the question goes farther and says,
6 well, you don't even know if Teva did any testing, I think
7 that violates 602 and it's outside the scope of her topic.

8 And that's why we have a few objections on that
9 ground, that this is one of them.

10 SPECIAL MASTER VANASKIE: All right. David?

11 MR. STANOCH: Your Honor, we're asking this witness
12 about the regulatory communications with the FDA about what
13 testing was done and the representations made in that
14 communication to the FDA. We just heard on Your Honor's prior
15 rulings that what Teva or FDA did or did not do or did not say
16 about testing is fair game.

17 So if Teva is going to make a statement in the letter
18 to the FDA about what testing it did or did not do, I can
19 certainly ask and did ask that witness what other testing may
20 be out there as to the veracity of the statements made in
21 those letters to the FDA.

22 MS. LOCKARD: The other thing I'll mention about
23 this, Your Honor, is that she's actually asked the same
24 question twice. And so in the full designation, you know,
25 she's asked at line 15, she gives a response, and then she's

1 asked again on page 111, line 7. "Again, you don't know one
2 way or another?"

3 And in our meet and confers, according to my notes, I
4 said, we would withdraw the objection to the first question if
5 the second time the question was asked is taken out.

6 So I think as a -- you know, as a resolution of this,
7 if -- we would agree to the first part, the first question and
8 answer ending at 111, line 6, if he takes out the remainder of
9 that designation and the answer in the following designation.

10 MR. STANOCH: Your Honor, I don't want to belabor it.
11 The first question, she says, "Oh, perhaps it doesn't specify
12 everything." I'm quoting. So I follow up then on that
13 because she opened the door. Right?

14 "Well, you don't actually know, Ms. Gray, one way or
15 the other, do you, if it doesn't specify everything or not?
16 Perhaps there's something else."

17 She injected that in her answer, and Ms. Lockard
18 wants to take away my cleaning that up and following up on the
19 witness's answer, implying, wrongly, that perhaps there is
20 something else out there. I just don't know.

21 I don't think it's appropriate to cut it off. It's
22 not cumulative.

23 MS. LOCKARD: That's why it's inappropriate testimony
24 to reach the jury, because she doesn't know. And it's outside
25 of her personal knowledge, and it violates Rule 602.

1 SPECIAL MASTER VANASKIE: I agree. The testimony
2 that follows the question at page 110, line 15, through page
3 110, line 20 should be stricken. In other words, I sustain
4 the objection and disallow that exchange in its entirety.

5 MR. STANOCH: I'm sorry, you said 110, 15 through
6 110, 20.

7 Do you mean the entire designate- -- the designation
8 was 110, 15, through 111, 12.

9 SPECIAL MASTER VANASKIE: That is out, as well as the
10 designation that's out at 111, line 17 to 20.

11 MR. STANOCH: Okay. So both of those are out. Got
12 it.

13 SPECIAL MASTER VANASKIE: Both of those are out.
14 That will take us to page 113, line 22.

15 MS. LOCKARD: So on this one, Your Honor, the only
16 part of this that we object to are lines 115, 3 to 7.

17 SPECIAL MASTER VANASKIE: Page 115, lines 3 to 7?

18 MS. LOCKARD: Yes. So we only object to 115, lines 3
19 to 7.

20 MR. STANOCH: Your Honor, based on your last ruling,
21 I agree that lines -- 115:3 to 7 should come out under the
22 same logic, as well as the answer in the ensuing designation.

23 SPECIAL MASTER VANASKIE: Right. So that would be
24 page 115, lines 15 through 21.

25 MR. STANOCH: Correct. So 115, 3 through 7, the

1 question, out. 115, 15 to 21, the answer, out.

2 SPECIAL MASTER VANASKIE: Are you with us on that,
3 Victoria?

4 MS. LOCKARD: Yes. I think we understand. So that's
5 correct. And I believe that's it for Liz Gray.

6 MR. STANOCH: Yep.

7 SPECIAL MASTER VANASKIE: Yes. I think that is.
8 That's why I chose that one.

9 MR. STANOCH: One down, Your Honor. Very nice.

10 SPECIAL MASTER VANASKIE: It's not going to go as
11 well.

12 The next witness I had is a Torrent witness, I
13 believe. And that would be Kelly Gegenheimer.

14 MR. NIGH: Yes, Your Honor.

15 MR. RAE: Yes, Your Honor.

16 SPECIAL MASTER VANASKIE: This gets hard for me to
17 follow here.

18 I'll tell you where I'm at, and then you can
19 straighten me out. I'm at line 21 of the spreadsheet, page
20 73. See, that's where I have trouble with this.

21 I guess it would be page 97 of the transcript, lines
22 23; page 98, line 3.

23 MR. RAE: Your Honor, I believe Torrent withdrew that
24 designation.

25 So the first area that I have where there is an

1 objection apparently is that plaintiffs object to our
2 counter-designation from -- on lines 101:4 to 101:17.

3 SPECIAL MASTER VANASKIE: On what page?

4 MR. RAE: Our page 101, line 4 to page 101, line 17.

5 SPECIAL MASTER VANASKIE: Let me get there.

6 MR. NIGH: It's line 24 on the spreadsheet.

7 SPECIAL MASTER VANASKIE: Thank you.

8 Daniel, do you want to respond to the objection?

9 MR. NIGH: Yes, very briefly.

10 We believe that it's nonresponsive. This is
11 Torrent's counter-designation to our designation pages 100,
12 line 10 to pages 101, line 3. And then they want to counter
13 for 101 to -- or line -- page 101, line 4 to line 17. And we
14 believe it's nonresponsive, primarily.

15 MR. RAE: Your Honor, this is Jacob Rae for Torrent.

16 Our position is that, as Ms. Lockard have discussed
17 earlier, counter-designations reflect information and in
18 fairness should be considered with the testimony surrounding
19 it.

20 Here Mr. Gegenheimer is clarifying that this line of
21 questioning about inquiries from finished dose customers is
22 generally consistent across all of the finished dose
23 customers. We think that's fair content for the jury in
24 understanding this line of questioning and to the extent that
25 there's, I think, any relevance to these questions from

1 pharmacy customers being directed to Torrent, which, frankly,
2 I'm not sure there is, this context is relevant to that issue.

3 So if Mr. Nigh wants to say that this whole line of
4 questioning is irrelevant, I'm not sure I'm going to disagree
5 with him about that. But this counter is fairly tied to the
6 testimony that it relates to and should be played along with
7 it.

8 SPECIAL MASTER VANASKIE: I agree. I'll overrule the
9 objection and allow that testimony to come in.

10 Now, the next one I have is at page 177 of the
11 transcript.

12 MR. RAE: Yes.

13 SPECIAL MASTER VANASKIE: This is line 29 of the
14 spreadsheet.

15 MR. NIGH: Yes.

16 SPECIAL MASTER VANASKIE: My inclination is to
17 sustain the objection.

18 MR. RAE: Your Honor, if I may.

19 SPECIAL MASTER VANASKIE: Yes, Jacob.

20 MR. RAE: This is a question that plaintiffs are
21 asking, where the witness, Mr. Gegenheimer here, I think
22 begins to answer the question before the question is finished.
23 So the question begins at line 17: "Okay. And does it
24 reference impurities? " The witness answers that question and
25 then begins to answer, there's cross-chatter with counsel.

1 And the answer that follows that we've counter-designated is
2 the full context that the witness is providing to explain why
3 this document doesn't reference impurities on it.

4 That context is important because this case obviously
5 is about impurities, but it's not about packaging
6 instructions, and there's no reason why packaging instructions
7 being provided to pharmacies, who are also not the plaintiffs
8 in this case and don't have any claims in this case, would
9 contain information about impurities.

10 This is blister stability data. Blister stability,
11 that's for the blister packs that products are packaged in to
12 provide them to the pharmacies. It's not about impurities.
13 And there's no allegation in this complaint that the
14 impurities come from the way in which products were packaged
15 or stored. It's uncontested in this case that the impurities
16 arose as a process issue with the way in which ZHP was
17 manufacturing the API.

18 And so the full context of this answer is really
19 important here to explain to the jury fairly why this sort of
20 information about impurities wouldn't be in this blister
21 stability data that is being provided to pharmacies.

22 SPECIAL MASTER VANASKIE: Daniel?

23 MR. NIGH: Your Honor, the question is simply: "In
24 this blister stability data, does it reference impurities in
25 the document?"

1 The answer is: No.

2 The rest of this is not responsive to whether or not
3 impurities are listed to the question, "Does it reference
4 impurities?"

5 The rest of it is a long, drawn-out response that
6 simply is explaining why it doesn't list it. That's not the
7 question.

8 SPECIAL MASTER VANASKIE: Yeah. No, I agree. I
9 sustain the objection and disallow that testimony.

10 MR. NIGH: Okay.

11 SPECIAL MASTER VANASKIE: The next one I have -- and
12 you can correct me on this if I'm wrong. I'm just trying to
13 follow these notes on the spreadsheet. It's at line 33 of the
14 spreadsheet. It deals with testimony at page 181, line 6 to
15 181, line 21.

16 MR. RAE: Yes, Your Honor. And that's our objection.

17 The objection here is this is testimony that's being
18 designated about how Torrent deals with sales to pharmacy
19 customers of product that's been sitting in the inventory for
20 a long time. It's extremely irrelevant to this case. It's a
21 question about kind of -- nothing about this case has to do
22 with how product -- Torrent manages its inventory with respect
23 to products that have been sitting on the shelf for a while.

24 It's prejudicial because the implication of this
25 question is that Torrent is engaged in some sort of process to

1 kind of provide some sort of extreme discounting or the
2 discussion of destroying product that comes up in the answer
3 to this question, all of which is irrelevant, and plaintiffs,
4 I assume, want to play this to get in front of the jury sound
5 bites about destruction of product that are, frankly,
6 irrelevant to this case.

7 SPECIAL MASTER VANASKIE: Daniel?

8 MR. NIGH: Your Honor, that's not the reason at all.

9 The defendants have put great length to try to state
10 that the drug has some efficacy and, therefore, it has some
11 value, even though it's been contaminated with a carcinogen
12 that's, you know, 300 times the acceptable level.

13 So here, we actually get to see another similar sort
14 of alternative, a drug that's getting close to its expiry, and
15 Torrent admits that a drug that gets close to its expiry,
16 takes an extreme discount on that product. And that actually
17 gives the jury some sort of guidance, whereas Torrent and the
18 other defendants have given very little guidance as to how to
19 value a product that may have some efficacy but is
20 contaminated with a carcinogen 300 times the safe level that
21 the FDA set.

22 SPECIAL MASTER VANASKIE: Yeah, I think it's tied in
23 closely enough. I'll sustain the objection and disallow the
24 testimony on page -- this is hard -- 181, lines 6 to 21.

25 All right. I just want the record to be clear.

1 MR. NIGH: Sure.

2 SPECIAL MASTER VANASKIE: It might be easier if I
3 look at the screen.

4 I think the next excerpt to address is dealt with at
5 line 39 of the spreadsheet. The testimony is at page 191,
6 line 13, to page 193, line 1.

7 MR. RAE: Yes, Your Honor. The objection here is a
8 completeness objection with respect to our counter. So I
9 think it's probably primarily plaintiffs' objection to our
10 counter that we would be addressing here, but I'm happy to go
11 first if that would be helpful.

12 SPECIAL MASTER VANASKIE: No. Let's hear from
13 Daniel.

14 MR. NIGH: Yeah, I would just say it's -- you know,
15 again, it's not responsive to the question, their
16 counter-designation.

17 MR. RAE: And, Your Honor, I think this is just --
18 this is another example of we just want the witness's full
19 answer to get played for the jury. It's the complete answer
20 to the witness explaining the context of the first paragraph
21 of his answer as to -- the question is about who these sheets
22 are sent to. He explains who they're sent to, and he explains
23 why they would be sent to customers and in what context they
24 would be sent to customers. It's closely tied to the
25 question.

1 SPECIAL MASTER VANASKIE: You would cut it off at
2 page 193, line 1?

3 MR. RAE: I don't want to speak for Mr. Nigh, but
4 that, I believe, is where they want to cut it off. That's
5 what their designation was.

6 MR. NIGH: That's correct, Your Honor.

7 SPECIAL MASTER VANASKIE: You want to take it from
8 line -- page 193, line 2 to line 12?

9 MR. RAE: That's correct, Your Honor.

10 MR. NIGH: Your Honor, I would just point out, again,
11 that: "Who at Torrent, besides you, sent out these HDMA
12 sheets?" That's the question.

13 So the rest of that is not responsible (sic) to who
14 is sending out those sheets.

15 MR. RAE: Your Honor, it's -- as Ms. Lockard
16 mentioned earlier, it's not simply a question of whether or
17 not it's responsive to the question. It's whether or not our
18 counter-designation is something -- this wasn't objected to at
19 the time. There was no, like -- and independent of that, the
20 question is whether or not this is, in fairness, something
21 that should be played alongside the designation of plaintiffs,
22 whether or not it provides context to the jury for the
23 questions that they're asking, not whether or not it conforms
24 precisely to the exact question that they asked.

25 MR. NIGH: Your Honor, just one thing there, which

1 is -- I think Your Honor knows this, obviously, but, you know,
2 we were asked not to move to strike, so that's why there's not
3 an objection there at the time.

4 SPECIAL MASTER VANASKIE: Right.

5 I will sustain the objection and disallow the
6 testimony from lines 2 through 12 on page 193.

7 The next one I have is page 196, line 17 to page 197,
8 line 2.

9 MR. NIGH: Was there an objection to 195:9 to 24?

10 SPECIAL MASTER VANASKIE: There is. Thank you.

11 MR. RAE: There is.

12 And, Your Honor, the objections here -- it may make
13 sense to talk about both the objection on page 195 and the
14 one -- the question on 196 together is -- these are questions
15 about a material safety data sheet. These are safe handling
16 instructions that are provided to pharmacy customers about
17 environmental risks with products, handling risks, employee
18 safety.

19 The line of questioning here is focused on whether or
20 not there was disclosure of toxicological issues or
21 carcinogenic issues with valsartan product in the context of
22 these material safety data sheets. And this case isn't
23 about -- again, these aren't -- this case is a breach of
24 warranty case, a consumer fraud case and a fraud upon
25 third-party purchaser insurance companies.

1 These are communications that are being made to
2 pharmacies and to wholesalers about how to handle this
3 product. They aren't representations or warranties that are
4 being made to any of the plaintiffs or class members in this
5 case. They are not relevant to the issues about which those
6 folks claim to have been misled, and it's extremely
7 prejudicial to allow a line of questioning about whether or
8 not carcinogenic risks that Torrent didn't even know about at
9 the time were being disclosed to pharmacy customers or about
10 whether -- or to allow questioning that implies that these
11 customers somehow changed the way they approached asking
12 routine questions about material safety data sheet content
13 after the recall took place, which there's no evidence
14 happened and which the answer here makes clear is not
15 something that happened.

16 But the jury hearing the question, there's no way to
17 reverse the impact of even being asked that question and the
18 suggestion that there was a change in Torrent's conduct that
19 took place. That question in and of itself is going to
20 prejudice to the jury. It's going to put ideas in their mind,
21 this didn't matter for the way in which these material safety
22 data sheet questions were asked by pharmacists.

23 MR. NIGH: Your Honor, there's a lot to unpack there,
24 but if I can.

25 SPECIAL MASTER VANASKIE: Go ahead.

1 MR. NIGH: This information goes to the heart of our
2 case. It is -- in fact, the 30(b) (6) notice says: Torrent's
3 oral and written communications with its valsartan finished
4 dose customers or other downstream defendants -- which
5 includes the wholesalers, retailers, consumers, TPPs --
6 regarding quality, purity or contamination issues regarding
7 the Torrent finished dose.

8 Then we can look through multiple of these where
9 that's exactly the sorts of information that Kelly Gegenheimer
10 was put up to ask. That's her -- in her role as 30(b) (6), she
11 is responding to those statements and other ones, Torrent's
12 oral and written statement to finished dose manufacturers,
13 wholesalers, retailers and consumers, with regard to the
14 contents and purity of Torrent's finished dose.

15 So this goes to -- you know, one of the main issues
16 is that there is a representation and a warranty here that
17 this product is free of these contamination and it includes
18 genotoxins.

19 So it doesn't have to be a warranty specifically
20 under many of the different state laws. It doesn't have to be
21 a warranty specifically handed down from Torrent that makes
22 its way to the pharmacy. It could be a warranty from Torrent
23 to a wholesaler that makes its way to a pharmacy.

24 And this is proving up one of the chinks to the chain
25 that shows -- or one of the pieces of the chain that shows a

1 warranty that ZHP first made to Torrent and that Torrent is
2 passing along to its customers.

3 MR. RAE: Your Honor, if I may. Mr. Nigh --

4 SPECIAL MASTER VANASKIE: You may, Jacob. Go ahead.

5 MR. RAE: Thank you, Your Honor.

6 Mr. Nigh spoke about warranties to pharmacies and
7 questions to retailers and pharmacies. And undeniably that's
8 one of the topics that Ms. Gegenheimer was asked about in
9 connection with her deposition here, which relates to all of
10 the valsartan cases in this MDL.

11 But for this trial, this trial is about
12 representations and warranties that were made to the
13 third-party purchasers. Mr. Nigh did not say that anything in
14 this line of questioning relates to representations or
15 warranties or information that was passed along to third-party
16 purchasers.

17 So introducing it in this trial is unfairly
18 prejudicial. It will be confusing to the jury because the
19 jury is not going to understand how this connects back to any
20 of the allegations, any of the elements of any of the issues
21 that they're expected to rule upon.

22 MR. NIGH: Your Honor, again, if I can comment,
23 that's actually not the law for many of the states. The
24 warranty doesn't actually have to be specifically made from
25 Torrent to a third-party payor. The law can be a warranty is

1 made from Torrent to an entity such as a wholesaler, which is
2 what this warranty is. It's a warranty from Torrent to the
3 wholesaler.

4 There are multiple states that do not say the
5 warranty has to be made specifically to the third-party payor.

6 SPECIAL MASTER VANASKIE: All right. I will allow
7 the testimony at page 195, line 9 to line 24.

8 Now we're on 196, line 17 to 197, line 2.

9 MR. NIGH: Your Honor, I think this is sort of the
10 same -- this is the same issue. It's just explaining that
11 prior to 2018 would this same sort of warranty be made to
12 these customers.

13 MR. RAE: Your Honor, I would agree that this is
14 essentially the same issue. I would note that this issue and
15 this question specifically asks about toxicological issues and
16 carcinogenic issues and that that -- that discussion of
17 carcinogenicity and -- like specifically ties to issues that
18 the parties are still disputing with respect to the scope of
19 risk-benefit or general causation testimony that might be
20 coming and that Judge Bumb has not yet ruled upon exactly
21 what's going to be permissible at the trial on those sorts of
22 topics.

23 SPECIAL MASTER VANASKIE: So I think what I'd like to
24 do is reserve ruling until I understand what Judge Bumb is
25 going to allow with respect to general causation and

1 carcinogenic issues.

2 MR. NIGH: Yes, Your Honor. I would agree with Jacob
3 that in terms of -- there's even been mention of not using the
4 word "carcinogenic."

5 SPECIAL MASTER VANASKIE: Right.

6 MR. NIGH: We have to see how that plays out. But
7 other than that reservation, we believe that this testimony is
8 admissible.

9 SPECIAL MASTER VANASKIE: Well, we'll reserve on it.
10 And you can come back to me once you have more guidance from
11 Judge Bumb with respect to, for example, the use of the term
12 "carcinogenic." All right?

13 MR. NIGH: Yes, Your Honor.

14 MR. RAE: Thank you, Your Honor.

15 SPECIAL MASTER VANASKIE: The next objection I have
16 is on page 205. You have something different than that?

17 MR. RAE: That's what I have next, Your Honor, as
18 well. And in fairness, I think that the testimony here runs
19 through -- it's -- the next three lines of the spreadsheet is
20 all kind of a set of testimony that runs together.

21 SPECIAL MASTER VANASKIE: Okay.

22 MR. RAE: The objection here is that -- the
23 questioning here, this kind of ties back to the same issue
24 of -- to a large degree it's a relevance issue, and it's just
25 a confusing issue of why we're talking about particular retail

1 pharmacy customers who are purchased and what customers
2 Ms. Gegenheimer highlighted in this spreadsheet.

3 I'm -- I don't want to kind of spend a lot of time
4 discussing -- I don't have a lot to say about this objection,
5 and I'm happy to defer to Your Honor's decision and instincts
6 as to what to do with this one.

7 SPECIAL MASTER VANASKIE: Go ahead, Daniel.

8 MR. NIGH: Just briefly, this is just to establish
9 that customers -- again, we need to establish the -- to the
10 degree that we need to establish the chain of supply and the
11 chain of communication and the ability as to which Torrent has
12 the ability to communicate. That's precisely what this does.

13 SPECIAL MASTER VANASKIE: All right. I would allow
14 the testimony.

15 This is at page 205, line 8, to 205, line 23.

16 And then page 206, line 4, to 206, 24.

17 MR. NIGH: And then I think it's 207:4 to 207:6 as
18 well.

19 MR. RAE: I would agree with Mr. Nigh's statement,
20 Your Honor.

21 We also have a counter-designation at 207:1 to 207:3,
22 which is --

23 SPECIAL MASTER VANASKIE: Go ahead, Daniel.

24 MR. NIGH: I really don't understand why that's being
25 counter-designated other than to try to take up time. Because

1 it's Kelly Gegenheimer's stream of thought that it doesn't
2 even complete. He doesn't actually answer anything there.

3 And he says, "And I think I was basically
4 highlighting at this time that those were not -- what was I
5 highlighting here?"

6 There's no response there.

7 SPECIAL MASTER VANASKIE: It's a stream of
8 consciousness, but it's all part of the answer. I would allow
9 it. And it's not taking up much time.

10 MR. NIGH: Okay.

11 SPECIAL MASTER VANASKIE: The next one I have is line
12 47 of the spreadsheet, page 210, line 10, to page 211, line
13 13.

14 MR. RAE: Your Honor, we had withdrawn that objection
15 as well. I think maybe -- I know I had sent -- I apologize
16 for this. I think I had sent plaintiffs a copy that had some
17 of our objections withdrawn, and it seems like maybe the copy
18 that was transmitted to Your Honor doesn't reflect those.

19 But we've withdrawn that objection as well as the
20 next two objections in the counter in your -- that are on the
21 spreadsheet that were sent to Your Honor, I think.

22 So the next objection that I have is the one that
23 begins on page 395, line 10 of the transcript.

24 SPECIAL MASTER VANASKIE: Is that what you have as
25 well, Daniel?

1 MR. NIGH: I'm working off an outdated one, but yes,
2 that sounds correct.

3 SPECIAL MASTER VANASKIE: The one I'm working on is
4 certainly outdated.

5 MR. NIGH: I think you and I have the same one. I
6 apologize if we made that mix-up.

7 SPECIAL MASTER VANASKIE: It's a lot of work, and I
8 understand that. And it's hard to keep track of everything.

9 So we're going to page 395, line 10, to page 395,
10 line 14.

11 MR. RAE: Correct, Your Honor. So this is Torrent's
12 objection.

13 This is an issue that we think, as we noted to Your
14 Honor, was decided in one of our motions in limine that Judge
15 Bumb already addressed. The motion in limine related to the
16 use of this email. And the email refers to the purchase of
17 cheaper Chinese API. And the motion in limine that we filed
18 was that plaintiffs cannot pursue lines of questioning or use
19 this document and mischaracterize it as if it's cheap Chinese
20 API instead of cheaper Chinese API, with there being an
21 important distinction between cheap and cheaper, as to the one
22 meaning inexpensive and the other meaning relatively less
23 expensive.

24 The question here is built off of a chain of
25 questioning where plaintiffs' counsel implies to the witness

1 that this email uses the term "cheap" and then asks a question
2 about Torrent's use of "inexpensive Chinese API for its
3 valsartan production."

4 We think this is squarely barred by Judge Bumb's
5 sustaining of our motion in limine on this topic.

6 MR. NIGH: Judge, the motion in limine ruling was
7 very -- very specific and very narrowed. And it simply is
8 that we not misquote the document from cheap to cheaper.

9 What's been designated here doesn't even use the word
10 "cheap" the entire time. The questions above may use the word
11 "cheap," but that's not the issue.

12 And the issue is also not that we can't use the word
13 "cheap." It's just that we can't misquote the document as
14 saying cheap as compared to cheaper.

15 And so this is like the highlight of what would be
16 admissible, especially through the -- as we saw in the
17 argument, what the judge is saying, that it's not excluded to
18 be able to talk about that the Chinese API was inexpensive.

19 And that's the question we posed in this. And the
20 witness agrees that he understood that as of January 5, 2015
21 they were using an inexpensive Chinese API.

22 SPECIAL MASTER VANASKIE: This is just lines 10 to
23 14?

24 MR. NIGH: Yes.

25 SPECIAL MASTER VANASKIE: On page 395, at least for

1 now.

2 Yeah. I would overrule the objection and allow the
3 testimony.

4 MR. RAE: Your Honor, can I be heard briefly?

5 SPECIAL MASTER VANASKIE: You may be heard. Sure,
6 Jacob.

7 MR. RAE: If you go back up to the prior page, this
8 line of questioning begins with questioning about the
9 document. It's established that what the language in the
10 document says is that uses the phrase "cheaper Chinese API."

11 Plaintiffs' counsel then goes on to ask a question
12 about cheap Chinese API and what the word "cheap" means. The
13 witness testifies that they have no idea what cheap means in
14 the context of this email.

15 Plaintiffs' counsel then asks, "Do you know what
16 cheap means in the ordinary world?"

17 The witness answers, "Cheap means would be
18 inexpensive in terms of cost."

19 That question, that phrasing of what cheap means in
20 the ordinary world is then what fuels the next question of, "I
21 agree with you. So you understood on January 5, 2015 that
22 Torrent was using inexpensive Chinese API for its valsartan
23 production. Correct?"

24 "Correct."

25 The inexpensive is just a substitute for the prior

1 question of "what does cheap mean." The question is literally
2 just asking -- counsel is saying that Torrent was using cheap
3 Chinese API for its valsartan production. That's exactly what
4 Judge Bumb ruled cannot come into evidence in this case.

5 These are not the witness's own words. The witness
6 did not inject the word "cheap" into this line of questioning.
7 The witness did not inject the word "inexpensive" into this
8 line of questioning, except through being asked what the word
9 "cheap" means.

10 MR. NIGH: Judge, this is way afar what Judge Bumb
11 ruled, and it's actually way afar even what the defendants
12 argued in front of Judge Bumb.

13 This was our concern the whole time, was that they
14 would try to use some difference between cheaper and cheap in
15 the questions and then go along this tangential road that
16 somehow everything is barred to ask any questions about this
17 document. It's absurd.

18 The ultimate question of what we designated simply is
19 even just asking him as of this date, was he aware that they
20 were using inexpensive Chinese API, period. We didn't
21 designate all the rest that he's pointing to. That one
22 question is all we designated, and he said "correct."

23 SPECIAL MASTER VANASKIE: No. I understand the
24 objection.

25 I will allow this testimony and overrule the

1 objection.

2 MR. RAE: Your Honor, I recognize the Court's ruling.

3 I want to make sure -- if I can point Your Honor to
4 Judge Bumb's ruling itself in the July 23rd hearing transcript
5 in our motion in limine, because I think it's important -- I
6 think Mr. Nigh has mischaracterized her ruling, and I think
7 it's important to look back at what Judge Bumb actually ruled,
8 if I can have your indulgence to do that.

9 SPECIAL MASTER VANASKIE: Sure. Absolutely.

10 MR. RAE: So on page 19 of the July 23rd transcript,
11 when this issue comes up, Judge Bumb begins by stating:
12 "References to 'cheap' versus 'cheaper.'

13 "Well, it is what it is. I mean, whatever the email
14 used is what should be said."

15 In response to that, Devora Allon, also counsel for
16 Torrent, responds: "Right. And I think that's the
17 distinction. The email says 'cheaper.' The plaintiffs
18 routinely say 'cheap.' Those two things are not the same."

19 Judge Bumb says: "Okay. So the evidence will be
20 'cheaper.' "

21 Okay. That's exactly the issue here. The issue here
22 is that this is not a question about cheaper. If this was a
23 question about using relatively less expensive Chinese API, we
24 may not be making this objection here.

25 But the question before this makes clear that the

1 "inexpensive" in this question is just a stand-in for the
2 cheap statement that Judge Bumb has ruled cannot come into
3 evidence in this case. It has to be what that email actually
4 said.

5 MR. NIGH: Your Honor, that's not the ruling. In
6 fact, they actually -- he didn't read out what I clarified
7 later, which was, I asked the Judge: Judge, this is simply
8 limited to misquoting the email from cheap or cheaper.
9 Because witness has answered all sorts of questions about this
10 issue. And the Judge said: You just can't misquote the email
11 as saying cheap when it says cheaper.

12 That was left off. I know Jacob probably doesn't
13 like that part of the ruling, but that's what the Judge ruled.

14 And then in the order that Torrent even submitted,
15 the order is very clear. We just can't misquote and use the
16 word "cheap." That's it.

17 MR. RAE: Your Honor, that's exactly what they're
18 doing here. They misquote the email. They lead the witness
19 down a line of questioning based on their misquoting of the
20 email, and then they are designating testimony that's premised
21 on their misquoting of the email.

22 SPECIAL MASTER VANASKIE: I understand your point,
23 Jacob, but the point of this limited five lines here, from
24 line 10 to line 14, just says: Using inexpensive Chinese API.

25 I know up above, the witness says cheap means

1 inexpensive in terms of cost. But they're not using the word
2 "cheap" here. They're using "inexpensive."

3 I think it's permissible. I'll allow that testimony
4 to come in.

5 MR. RAE: Thank you, Your Honor.

6 MR. NIGH: Thank you, Your Honor.

7 SPECIAL MASTER VANASKIE: I think now we go to --

8 MR. NIGH: Is it 684, line 8 to 685, line 22?

9 SPECIAL MASTER VANASKIE: Yeah. Line 60 of the
10 spreadsheet.

11 MR. NIGH: And that's day 2 of the transcripts, just
12 so Your Honor knows as well.

13 SPECIAL MASTER VANASKIE: Let me get there.

14 MR. RAE: Your Honor, I'm just going to interject
15 again.

16 SPECIAL MASTER VANASKIE: Go ahead.

17 MR. RAE: We actually withdrew these objections on --
18 from pages 684 to 687.

19 SPECIAL MASTER VANASKIE: Okay.

20 MR. RAE: So the next objection begins on page 695,
21 line 18.

22 SPECIAL MASTER VANASKIE: Okay. Let me get there.

23 (Court reporter clarification.)

24 SPECIAL MASTER VANASKIE: And Jacob was correcting
25 me, I think, to say that the next objection is what, Jacob?

1 MR. RAE: It is page 696, lines 10 to 13 is the
2 question, and line 18 to 22 is the answer.

3 SPECIAL MASTER VANASKIE: All right. And the
4 question at 696, line 10 is: "And would that safety data
5 sheet talk about potential -- that there is no potential
6 impurities or carcinogens?"

7 And the answer is at lines 18 to 22: "That's my
8 understanding that material safety data sheets are related to
9 hazardous material, environmental handling of the product."

10 MR. RAE: And, Your Honor, I think this is a similar
11 issue to the objection that we talked about earlier about
12 material safety data sheets. I think there's an additional
13 issue here of there being a lack of foundation for this
14 question. There's no grounding in kind of this actually being
15 content that's present in material safety data sheets. And
16 this also kind of ties back to the cancer, general causation,
17 carcinogenic, carcinogens issues that are still being cited by
18 Judge Bumb.

19 SPECIAL MASTER VANASKIE: Daniel?

20 MR. NIGH: Your Honor, the foundation was laid
21 previously in the deposition. In fact, we even saw some of
22 those foundations. So I don't know where the argument is
23 there.

24 We don't take these -- each of these lines in and of
25 itself as the foundation. So, you know, we talk all about

1 these requirements and the toxicological information,
2 including carcinogenic and all of those issues. Now we're
3 just further clarifying specifically what's to be in there.
4 And the witness clearly has the understanding. He responds --
5 he responds to the question.

6 I would say, I did notice that -- one hiccup, and I
7 don't know if you've got the same thing there. I think 696,
8 lines 10 to 13, do need to be included, because that's the
9 question. And then the answer would be 18 to 22.

10 SPECIAL MASTER VANASKIE: Correct.

11 MR. NIGH: So that's the rest of my response.

12 SPECIAL MASTER VANASKIE: It seems to me to fall
13 within the same area that I reserved on, and I'll reserve
14 ruling on this one.

15 I expect what happens is you'll bring it back to me.
16 All right?

17 MR. NIGH: Yes, Your Honor.

18 SPECIAL MASTER VANASKIE: Once you've received
19 further guidance from Judge Bumb.

20 MR. RAE: And, Your Honor, I think that same issue is
21 going to apply to the next -- or, frankly, the last couple of
22 objections, which are in the same line of questioning of
23 Kelly Gegenheimer.

24 If Mr. Nigh will agree, we can potentially move on to
25 the next witness.

1 SPECIAL MASTER VANASKIE: This would be at page 696,
2 line 18 to page 697, line 22?

3 MR. RAE: Yes. And the objection there is from --
4 just to the question at 696, line -- sorry, yeah. And then
5 there's another one on 697, line 16 to 698, line 3.

6 SPECIAL MASTER VANASKIE: So we'll reserve ruling on
7 that.

8 MR. NIGH: Yes.

9 And then, Your Honor, I don't know if there's any
10 objection to the rest of -- after 698:4 to 698:22. It doesn't
11 appear from the sheet, but none of that says carcinogenic in
12 it.

13 MR. RAE: To clarify, we do not have an objection to
14 the rest of that testimony.

15 SPECIAL MASTER VANASKIE: So the testimony at page
16 698 -- I better get this right -- 698, line 2, to 698, line 22
17 comes in?

18 MR. NIGH: 698:4 to 698:22.

19 SPECIAL MASTER VANASKIE: Okay.

20 MR. NIGH: Do you agree, Jacob?

21 MR. RAE: Yes, I agree.

22 SPECIAL MASTER VANASKIE: 698:4 to 698:22 will come
23 in.

24 And that's it for Kelly Gegenheimer?

25 MR. NIGH: Yes, Your Honor.

1 MR. RAE: Yes, Your Honor.

2 SPECIAL MASTER VANASKIE: What I'd like to do now is
3 proceed to Sushil Jaiswal.

4 Tell me how you pronounce that.

5 MR. RAE: Your Honor, I think you -- you got
6 Dr. Jaiswal's last name correct. His first name is Sushil.
7 Sushil Jaiswal.

8 SPECIAL MASTER VANASKIE: Okay, thank you.

9 MR. NIGH: Your Honor, is it possible to take a brief
10 break?

11 SPECIAL MASTER VANASKIE: Yes. Let's take a
12 ten-minute break.

13 MR. NIGH: Okay. Thank you, Your Honor.

14 MR. RAE: Thank you, Your Honor.

15 (Recess at 10:40 a.m. until 10:49 a.m.)

16 SPECIAL MASTER VANASKIE: So we're on
17 Sushil Jaiswal's deposition.

18 And where are we starting here?

19 Go ahead, Jacob.

20 MR. RAE: I think our first objection is to the
21 testimony at lines -- page 35, line 10 to page 35, line 17.

22 MR. NIGH: I have the same.

23 SPECIAL MASTER VANASKIE: All right.

24 MR. RAE: And, Your Honor, I think the 403 objection
25 primarily relates to the kind of cancer issues that we've been

1 discussing. So unless Your Honor wants me to address that,
2 I'm going to focus on the foundation objection.

3 The foundation objection is -- these are questions
4 about a document. And if Your Honor looks at page 34, line 8
5 to 10 of this transcript, just a page earlier, counsel asks
6 the witness: "Okay. Have you ever seen this document
7 before?"

8 Answer: "No."

9 And so our foundation question is to the questions
10 that proceed to ask this witness about the content of this
11 document that the witness has already testified they've never
12 seen before.

13 SPECIAL MASTER VANASKIE: All right. Daniel?

14 MR. NIGH: Your Honor, the first two days of this
15 transcript are -- he's being put up in his capacity as a
16 30(b) (6) witness. And just to make that clear, like, he's not
17 just, you know, here on a couple of the topics. He is here
18 for nearly every single topic that we addressed in our
19 30(b) (6) notice. There's a couple other witnesses that have a
20 few topics, like Gegenheimer had a few on communication. But
21 he is here for testing of valsartan API and finished dose, and
22 there's all sorts of questions in there. He's here on quality
23 assurance and quality control activities, which, clearly, in
24 the quality control, we can see lots of information about --
25 including genotoxic impurities and what do you do about

1 genotoxic impurities, how do you evaluate those. He's in
2 there for process development. And there's all sorts of
3 information there on NDMA, NDEA, what's your knowledge, what's
4 your evaluation, what did you do in terms of doing a risk
5 assessment related to these issues. You know, all sorts of
6 information here.

7 So, to me, actually, the very purpose that Jacob is
8 pointing out is the very purpose that we would go into this,
9 because he's put up to speak on behalf of the company in
10 regards to these topics. And the fact that he's never seen
11 this document when he's put up to speak on behalf of the
12 company on their risk assessment is troubling.

13 He hasn't seen the document that talks about NDMA.
14 You know, one of the key documents, WHO, 2002 on NDMA, and he
15 hasn't seen it. And so now we are going to ask him questions
16 that are related to issues within it to see if he's understood
17 the content within there, which is fair game as well, to see
18 if he knows those answers, because maybe he hasn't seen the
19 document, but maybe he's learned some other way about
20 information that's in the document. And so we're asking that
21 information as well.

22 And this -- again, this is on behalf as a 30(b) (6)
23 witness, you know, in these first couple of days.

24 Now, I would say, Jaiswal is also the head of quality
25 and control at Torrent. He is their lead analytical chemist.

1 He's the one responsible for finding -- for detecting
2 impurities, identifying those impurities. So he would be --
3 the buck stops here; he's the guy. And that's why there's so
4 much designated from Jaiswal.

5 SPECIAL MASTER VANASKIE: Because he's a 30(b) (6)
6 witness, I don't think the lack of foundation objection is
7 well taken. So I would overrule that objection on page 35,
8 lines 10 to 17.

9 And the same would hold true with respect to page 36,
10 line 16 to page 37, line 6.

11 MR. RAE: Understood, Your Honor. And I just want to
12 be -- make sure that it's clear. My understanding is that we
13 are not dealing with our objections as they relate to the
14 discussion of cancer and carcinogenicity.

15 SPECIAL MASTER VANASKIE: Correct.

16 I'm sorry to interrupt you, Jacob. That is correct.
17 We're not dealing with that objection. We'll reserve ruling
18 on that aspect of it pending Judge Bumb's clarification. All
19 right?

20 MR. RAE: Thank you, Your Honor.

21 SPECIAL MASTER VANASKIE: Now, is the next excerpt at
22 issue on page 49, line 20? Or what do you have?

23 MR. RAE: We have an objection at page 41, line 11 to
24 17.

25 And I think -- but I think that we can put this in

1 the same category as what we just discussed. My understanding
2 is that Your Honor's foundation ruling would apply equally to
3 our -- prior ruling would apply equally to our foundation
4 objection here, and our 403 objection is one that we're
5 reserving.

6 SPECIAL MASTER VANASKIE: Correct.

7 MR. NIGH: I agree, Your Honor.

8 MR. RAE: So then, yes, the next one would be the
9 objection on page 49, line 20 to 50, line 4.

10 SPECIAL MASTER VANASKIE: Let me get to that.

11 MR. RAE: And, Your Honor, this is -- I think, again,
12 this also -- this testimony also kind of falls into the same
13 bucket of kind of discussion of genotoxicity, which is going
14 to relate to issues that Judge Bumb is going to decide.

15 But the objection that we made as well is a 701
16 objection, which is -- the question here is asking Dr. Jaiswal
17 to provide kind of an abstract opinion testimony about what
18 the term "genotoxicity" or the phrase "genotoxicity in the
19 body" means. And we don't think that that's an appropriate
20 usage of Dr. Jaiswal either as a fact witness or as a 30(b) (6)
21 witness.

22 SPECIAL MASTER VANASKIE: Any response, Daniel?

23 MR. NIGH: Yes, two things. One, when he's defining
24 what genotoxic means, he says genotoxicity in the body. He's
25 the one that uses those terms. So it's not an expert opinion,

1 it's just his knowledge. He is an analytical chemist. He's
2 the head analytical chemist for the company. He possesses
3 this knowledge. Clearly, he's the one speaking in these terms
4 if you just look at the questions right above. And so for him
5 to be able to define his own terms, that's not seeking an
6 expert opinion.

7 SPECIAL MASTER VANASKIE: I'll overrule the objection
8 and allow the testimony at page 49, line 20, to page 50, line
9 4.

10 And now are we on page 51, lines 1 to 4? Is this the
11 same --

12 MR. NIGH: The next objection I have is page 55, line
13 2 to page 55, line 8.

14 Is that right, Jacob?

15 MR. RAE: Yes, I agree.

16 SPECIAL MASTER VANASKIE: Okay. We're there then.

17 MR. RAE: To be clear, I think the objection here
18 really relates to the kind of both introduction to the exhibit
19 and then the questioning which is from 55, line 12 to 23.

20 The objection here is this is a document about
21 European regulatory standards from 2006. This case is about
22 US, the sale of products in the United States. It's about
23 United States regulatory standards.

24 The defendants had a motion in limine on this issue,
25 which Judge Bumb ruled on and ruled that foreign regulatory

1 standards are not going to come into evidence in this case.
2 And we think that if our 401 and 403 objections parallel the
3 arguments that we made in that motion in limine, and we think
4 that Judge Bumb's ruling on that issue squarely applies to
5 this testimony.

6 And I can point Your Honor to where that argument
7 happened in front of Judge Bumb and her ruling, if that would
8 be helpful.

9 SPECIAL MASTER VANASKIE: Let's hear from Daniel
10 first.

11 MR. NIGH: Yes, Your Honor. First off, I think that
12 that doesn't give the full meaning of the ruling. Keep in
13 mind that these are guidelines that guide -- that these are
14 regulatory statements that guide Torrent in what they're
15 supposed to be doing, and they're making representations based
16 on those regulatory guidelines as well.

17 And the other thing is, I think it's important to
18 also note that the defendants have multiple times, including
19 the *Daubert* hearing, have continued to throw up the ICH
20 guidelines.

21 And these guidelines here are the ancestor, the
22 predecessor to those guidelines. And they speak in detail in
23 terms of NDMA genotoxicity and what a company is supposed to
24 do in terms of detecting them, what are the limits that you
25 can detect them, what are you supposed to do in terms of a

1 threshold, all sorts of issues. And it's the predecessor to
2 the ICH Q3A guidelines that they're pointing to.

3 So we think for all those reasons -- again, he's put
4 up as the 30(b) (6) witness precisely on these topics. He's
5 also the lead analytical chemist. So this is precisely within
6 his wheelhouse.

7 SPECIAL MASTER VANASKIE: What about the argument
8 that Jacob made with respect to non-US standards?

9 MR. NIGH: Yeah. So, again, you know, I think he
10 has -- he has drawn that ruling and widened it much further
11 than it was. These standards, again, are the predecessor to
12 the ICH guidelines.

13 The ICH guidelines, in fact, you know, have a
14 footnote and in multiple places cite these guidelines. So to
15 say that this is just foreign, I mean, the ICH isn't based in
16 the US, but we all recognize that the ICH has to be followed
17 by US as well as this in terms of that it's incorporated,
18 cited, and the predecessor to the ICH guidelines.

19 MR. RAE: Your Honor, if I may, I think Mr. Nigh is
20 mischaracterizing what Judge Bumb ruled here. And if I can
21 point you -- I'm happy to point Your Honor to both the
22 argument that Ms. Lockard made on this issue, which
23 specifically references the EMA standards, the ones they're
24 being asked about here from the European Medicines Agency, and
25 where Judge Bumb rules that this evidence of these documents

1 can only come in if our witnesses say that we relied upon
2 these documents and these guidelines.

3 And this questioning does not involve reliance --
4 Dr. Jaiswal is going to appear live. I don't anticipate that
5 he's going to say that we relied upon this document or that
6 Torrent relied upon this document. But if that somehow comes
7 in, plaintiffs would have an opportunity to cross-examine him
8 on that issue when he appears live to testify.

9 But they can't just put in evidence on this document
10 unless it's to counter reliance testimony that doesn't exist
11 in this case, and frankly, isn't going to exist in this case.
12 And if it does happen to exist, they will have the opportunity
13 to counter it.

14 MR. NIGH: Your Honor, may I respond?

15 SPECIAL MASTER VANASKIE: You may respond.

16 MR. NIGH: It's very clear that they rely on the ICH
17 Q3A guidelines. Their expert talked all about them in the
18 *Daubert* hearing, Afnan did. On top of that, Jaiswal speaks to
19 it numerous times. This is cited in the ICH Q3A guidelines.
20 This is the predecessor to those guidelines. And so this
21 gives all sorts of information that talks about how you're
22 supposed to test for NDMA, dating back to 2006.

23 At the time that they were developing these drugs,
24 2011, 2010, you know, these would be the guidelines that --
25 that -- that they have to follow in terms of, you know,

1 genotoxic risk, compounds, how to test for them, you know, and
2 they're cited in the ICH Q3A guidelines that they're speaking
3 to.

4 MR. RAE: Your Honor, the ICH guidelines are
5 international guidelines. The reason why they are relevant to
6 this case is because they apply internationally. These are
7 European Medicines Agency guidelines. They apply to Europe,
8 not to the United States. And I think there's a very clear
9 line there, and it's a line that Judge Bumb recognized, and
10 it's a line that, frankly, has already been determined by
11 Judge Bumb for this case.

12 MR. NIGH: Your Honor, I disagrees.

13 SPECIAL MASTER VANASKIE: You say Dr. Jaiswal is
14 going to testify live?

15 MR. RAE: We are bringing Dr. Jaiswal live to testify
16 during our case.

17 SPECIAL MASTER VANASKIE: Go ahead, Daniel.

18 MR. NIGH: Your Honor, I would disagree yet again.
19 And I think this is a perversion of how ICH guidelines work.

20 The ICH is located in Europe. So when they say
21 they're international guidelines, oftentimes the ICH
22 guidelines cite other guidelines, which includes EMA, because
23 EMA has already fleshed out the issues in detail.

24 So to the extent that the ICH guidelines that they're
25 relying upon cite the EMA guidelines and discuss, you know,

1 definitions or how to look for these things, that's very clear
2 here, and they're relying on that document.

3 So this goes far afield of what they were asking
4 Judge Bumb. Here our argument is, this is square in line with
5 guidelines that regulate the international community because
6 it has been incorporated in the ICH guidelines.

7 SPECIAL MASTER VANASKIE: Jacob, you're going to
8 point me to or read from Judge Bumb's ruling?

9 MR. RAE: Yes, Your Honor. So this is in the July
10 23, 2024 transcript. Starting on page 274 is Ms. Lockard's
11 presentation of the issue here.

12 And you can -- you'll see in the transcript here,
13 Ms. Lockard -- let me get my bearings for a second.

14 Ms. Lockard discusses foreign regulatory standards or
15 guidance and indicates that kind of plaintiffs are going to
16 say that assuming defendants relied upon those, that that is
17 fair game.

18 "If there is something and they can establish that
19 one of the defendants relied on something from the EMA" -- the
20 European Medicines Agency, that's my clarification there --
21 "in formulating its response to the nitrosamine issue in the
22 US, then that's fair game. But just to bring in here what's
23 happening around the world or with Teva's facilities in other
24 countries not involving nitrosamine being sold in the US, I
25 think that should be excluded."

1 And Judge Bumb, on page 275, line 5 to 6, rules: "If
2 they rely on it, then you can -- then it opens the door for
3 you."

4 And then subsequently, on lines 14 to 15 of the same
5 page, reiterates, "If the witnesses say that they relied on
6 them, then it's relevant."

7 I can kind of keep going through -- she doesn't
8 have -- there's not a kind of clear single sentence
9 explanation here, but the clear import of this ruling is that
10 European Medicines Agency materials come in to the extent that
11 defendants relied upon them.

12 For example, in this argument, Mr. Slater on behalf
13 of plaintiffs made an argument that ZHP relied on certain
14 European Medicines Agency documents in its DMF. I'm not
15 counsel for ZHP, I am not opining on kind of that issue
16 specifically or what should be happening with ZHP's documents
17 and discussion of these guidelines or other guidelines with
18 respect to ZHP, but the ruling is very clear that reliance on
19 European Medicines Agency documents or use of European
20 Medicines Agency documents is limited to circumstances where
21 one of the defendants relied upon that document.

22 And that's not the case for this testimony. It's
23 certainly not the case that plaintiffs have established that
24 reliance. And I think there's potentially a different issue
25 when Dr. Jaiswal is testifying live at trial as to whether or

1 not there's some way that plaintiffs can establish reliance
2 such that they might be able to ask him questions about this.
3 I don't think they will be able to, but I think for purposes
4 of this deposition designation, it should not be coming in.

5 MR. NIGH: Your Honor, there's a huge difference
6 between what was argued at the hearing in terms of EMA
7 guidelines and their response to the nitrosamine recall.
8 That's post-2018. Here we're talking about guidelines that
9 were in place in 2006 that are cited by the ICH Q3A that they
10 rely on that defines in 2006, you know, what are the duties.

11 I mean, in this sort of scenario if Jaiswal were to
12 say, I don't rely on 2006, that would be more, you know,
13 problematic than anything else, because those are the
14 guidelines that regulate the international community at this
15 time.

16 They're cited by the ICH Q3A guidelines. So to say
17 that this has no -- this is just foreign, it's international.

18 MR. RAE: Your Honor, plaintiffs made exactly this
19 argument to Judge Bumb. Mr. Slater argued that -- and there's
20 also statements and information from the European, for
21 example, regulatory agency that talked about the dangers of
22 these drugs. That's all admissible for notice.

23 All the witnesses admitted that they were following
24 all of those guidelines. They all applied to the same drugs,
25 because the manufacturing facility was manufacturing for the

1 US and other places. That's the same argument that Mr. Nigh
2 is making here.

3 And Judge Bumb's response was not to accept that
4 notice argument and to refer back to, if the witnesses say
5 they relied upon them, then it's relevant. Implicit in that
6 statement is that notice argument doesn't work. They don't
7 get to come in for notice. They come in only if there is
8 reliance established.

9 SPECIAL MASTER VANASKIE: Anything else, Daniel?

10 MR. NIGH: Yeah. I would say that it's completely
11 different. We're talking about, you know -- the document that
12 he's talking about is not a document -- is not a -- hold on
13 one second.

14 Yeah. My point, again, Your Honor, the document he's
15 talking about is a document -- we're not talking about every
16 single regulatory document, you know, internationally that
17 might somehow have some bearing on what might put a defendant
18 on notice. These are the rules governing how to look for
19 genotoxic impurities that is cited by the ICH Q3A guidelines
20 on how to look for genotoxic impurities, you know, what are
21 the levels, what are the thresholds, all that sort of
22 information.

23 And this is the key of the dispute in the case, Your
24 Honor.

25 To say that somehow this is similar to some other

1 document that puts them on notice of one specific issue,
2 that's not what this document is. This document is the -- one
3 of the quintessential documents as to how the defendants are
4 supposed to test for genotoxic impurities, what are the
5 limits, including carcinogens like NDMA.

6 SPECIAL MASTER VANASKIE: All right. I've heard
7 enough. I'm going to rule and allow this testimony to be
8 presented.

9 I want to be clear for the record what we're talking
10 about, and that is from page 55, line 2 to page 55, line 8;
11 page 55, line 12 to page 55, line 23; and page 58, line 16 to
12 page 59, line 2.

13 Am I missing anything?

14 MR. RAE: No, Your Honor. And I understand your
15 ruling, and I just -- if I may be heard briefly.

16 I think Mr. Nigh has said that -- talked about other
17 documents. And I just want to be clear that the language that
18 I read from Mr. Slater a second ago from the hearing was a
19 reference -- I don't want to pretend to be able to read
20 Mr. Slater's mind, but he's clearly talking about European
21 guidelines from the EMA they want to submit for notice about
22 the risks of nitrosamines.

23 That is a reference to this exact document, that --
24 Judge Bumb has already addressed this exact issue and the
25 admissibility of testimony on this issue. And I want to make

1 sure that Your Honor is aware of that, because I think your
2 ruling is inconsistent with the prior ruling on the motion in
3 limine that Judge Bumb already made.

4 MR. NIGH: Judge, just to put a little bit more
5 flavor, because I think the record should be complete here.

6 You know, Judge Bumb -- what wasn't cited was
7 page 275, lines 21 to 25 of her ruling. And she said: "What
8 I said is if the witnesses say that they relied on them, then
9 it's relevant, right?"

10 Mr. Slater said: "If they --"

11 And she says: "They have to know about them."

12 That's her wording.

13 Well, Jaiswal clearly says he knows about this
14 document. That's what we asked him. It's page 59, line 9.
15 And he says: "But yes, I'm aware of this document."

16 Before that, it says: "Have you ever reviewed this
17 document as it pertains to your job? "

18 And he says: "Yes, I am aware of this document."

19 So clearly, in terms of the definition that even
20 Judge Bumb gives for reliance, you have to be -- they have to
21 be aware of the document. He clearly knows about the
22 document.

23 SPECIAL MASTER VANASKIE: I don't know that that gets
24 you far enough on the reliance question, but I do think it's
25 relevant. I do think it's admissible. I don't think there's

1 a conflict with Judge Bumb's decision. There may be. But I'm
2 deciding this issue on the basis of what is presented to me.
3 And I believe it's admissible and should come in. All right?

4 MR. RAE: Understood, Your Honor.

5 SPECIAL MASTER VANASKIE: It's very well argued. But
6 it seems to me that -- and maybe it's a disagreement with what
7 reliance means. It seems to me that's too narrow a test --
8 too narrow a standard to meet, that you have to rely on
9 something to be able to use it.

10 Now, I have the next area at issue starting at
11 page 70. Correct me if I am wrong on that.

12 See, I am having a little bit of trouble here. I
13 have the designations, and then I have objections on this
14 spreadsheet.

15 And I have objections to the testimony at page 70,
16 line 19 to 70, line 20. But maybe there's more at issue
17 there.

18 MR. NIGH: That's right, Your Honor. This is a
19 counter-objection. And we're objecting to their counters for
20 the next two.

21 So that starts with 70 to -- they want to add in
22 page 70, line 19 and 20 into it.

23 SPECIAL MASTER VANASKIE: Which is just a question.
24 Right?

25 MR. NIGH: Which is the question, but then they want

1 to also add in the answer.

2 But that's right. And so it's just a question. I
3 see no response, which is why I don't see why that would be
4 added.

5 MR. RAE: Your Honor, just to be clear, I think the
6 formatting of the spreadsheet may be creating a little bit of
7 confusion here. We're countering with the question and the
8 answer with the objection omitted.

9 And the question and the answer have -- fall between
10 a question that plaintiffs are asking about FDA limits -- the
11 interim limits that the FDA had established.

12 And they also -- they go on to ask subsequent
13 questions about these limits. And the question/answer that
14 we're designating as a counter, which we believe in fairness
15 needs to be played alongside that, is a question about how
16 those limits relate to what is permitted to be present in the
17 valsartan API that Torrent is purchasing from ZHP and that is
18 at issue in this case.

19 So the question before is if the FDA has a limit for
20 API only. The answer is that there's a limit for the finished
21 dose form.

22 The next question is -- that we want to counter with
23 is: "How much NDMA is allowed to be in the API?"

24 And we think that the witness's answer explaining
25 that issue should come in.

1 And then there's subsequent questions about the
2 relationship between the API and the finished dose product.

3 And we think that this context, frankly, will help
4 the jury understand that subsequent line of questioning about
5 the relationship between the finished dose product and the API
6 and kind of how these limits apply with respect to both forms
7 of the valsartan.

8 MR. NIGH: Your Honor, I guess to clarify this, the
9 information that they're looking to add is not responsive to
10 any of the questions that we designated. The questions we've
11 designated are actually very simple. They have other spots
12 they're going to add this same information in, which is they
13 want to constantly inject that they didn't know about the
14 carcinogen at the time, so there's no limit.

15 All we're asking at this point is: Well, what is the
16 FDA limit for the API? He responds back: It's .3 for the
17 finished dose form. So now we're going to go into this .3,
18 and we are going to show that all the products is over .3.

19 None of this has to do with, well, what was -- you
20 know, at sometime prior. That's not the questions here. In
21 fact, they get to answer that in other places, but it doesn't
22 need to be injected again here because it's irrelevant to this
23 line of questions.

24 MR. RAE: Your Honor, this is extremely relevant,
25 because the questions that they've designated, which we're not

1 objecting to, are vague as to the time frame in which we're
2 talking about these limits.

3 The question and answer that we're
4 counter-designating is clarifying the limits that we're
5 talking about don't apply at the time in which these products
6 were actually being produced and sold by Torrent. And that's
7 extremely relevant for the jury to understand when it's
8 listening to testimony about the fact that the API has NDMA
9 levels that are above this limit that came into existence in
10 the summer of 2018 and didn't previously exist.

11 SPECIAL MASTER VANASKIE: I will allow -- I will
12 allow the testimony at page 70, line 19 to page 70, line 20;
13 and 71, line 1 to 71, line 6.

14 Does that cover it?

15 MR. NIGH: Yes, Your Honor.

16 MR. RAE: Yes, Your Honor.

17 SPECIAL MASTER VANASKIE: The next one I have is
18 page 81, line 18 to page 82, line 2.

19 MR. RAE: Your Honor, this is our objection. And
20 this is primarily an issue of the evidence that's being
21 presented here being cumulative. The presence of NDMI and the
22 levels of NDMI in these products are not in dispute in this
23 case. The parties all agree that there was NDMA and NDEA at
24 least in some batches of the valsartan API -- with respect to
25 NDEA in some batches and NDMA in all batches of the valsartan

1 API that Torrent was using, and there's no dispute about the
2 levels.

3 We haven't objected to the testimony at lines -- on
4 page 79 that begins this line of questioning and establishes a
5 batch that was above the levels that plaintiffs want to point
6 to.

7 But we think that the testimony that runs for the
8 next five or six pages, beginning on line 82, that kind of
9 just walks through the math with respect to batch after batch
10 after batch is cumulative. It's prejudicial to have kind of
11 that process of just kind of walking through batches, an issue
12 that's not in dispute in the case, and presenting to the jury
13 over and over again the level of NDMA in those batches. And
14 that's the basis for our objection.

15 SPECIAL MASTER VANASKIE: All right. Daniel?

16 MR. NIGH: Your Honor, Torrent sold a lot of drugs.
17 They sold a lot of batches.

18 We lay out for each batch that it's, you know,
19 approximately 300 times over the threshold. And some aren't
20 quite 300 times. Some are a little bit less.

21 But for us to be able to lay out -- when we're --
22 we're talking about what takes up all of two or three minutes,
23 so it's not cumulative in that regard.

24 But we lay out. We calculate. He agrees it's -- you
25 know, for each batch, here's the amount that it's over the

1 threshold limit.

2 And that absolutely goes to one of the quintessential
3 issues here, especially in terms of when the defendants want
4 to raise that these drugs have some value, that being 300
5 times over the threshold is going to also make its way into
6 this case as well, because if there's going to be some sort of
7 evaluation on efficacy, there obviously has to be some sort of
8 value on how far over they went from the threshold level in
9 terms of safety.

10 SPECIAL MASTER VANASKIE: These objections are based
11 on Rule 403 of the Federal Rules of Evidence.

12 I don't think it's unduly prejudicial and not going
13 to confuse the jury.

14 So I'm looking at a series of objections on pages 82,
15 83, 84, 85, 86, 87 and 88.

16 I think it all comes in. The objection is overruled.

17 MR. RAE: Your Honor, understood on that.

18 And I think our next -- the next counter we have on
19 page 88:8 to 88:12, I'll let Mr. Nigh explain his objection,
20 but I think our position would be that in fairness, if all of
21 this testimony about these comparisons of levels to limits is
22 coming in, that our counter explaining that these limits did
23 not exist at that moment of time is necessary to come before
24 the jury in fairness as well.

25 SPECIAL MASTER VANASKIE: I agree with you, Jacob but

1 I think this does come in. So --

2 Go ahead, Daniel.

3 MR. NIGH: I was going to say, we think this is
4 similar to your prior ruling. We understand.

5 SPECIAL MASTER VANASKIE: All right. So 88, line 8
6 to line 12 is in.

7 Am I at page 89 now?

8 MR. RAE: Yes, Your Honor. And I think I would be
9 willing to stipulate that your prior ruling is going to govern
10 this objection.

11 SPECIAL MASTER VANASKIE: Covers this. Okay.

12 That's helpful, because I can't move ahead and put it
13 in context. But looking at this now, I'd say yes, that it
14 applies.

15 MR. RAE: So if it's helpful, the next objection I
16 have noted is on page 98, line 11 to 14, and our objection
17 here is that this simply isn't a question. There's no -- the
18 designated testimony doesn't include the question. It's just
19 attorney commentary.

20 MR. NIGH: Your Honor, to clear this up, I think it's
21 another typo. It should include 15 -- 98:11 through 98:15,
22 which the question is: "Do you see that one?" And below, you
23 can see the question where he answers "yeah," which is
24 designated in the designation below, 98:20 to 98:24. So the
25 answer is designated as part of that.

1 The next question is "Okay. And we see that number
2 again in the API stocks available chart."

3 And he says "okay."

4 So that's all -- you know, that's all part of that
5 information that should be included. But it should be 98:11
6 to 98:15.

7 MR. RAE: Your Honor, based on that alteration to
8 their designation, we'll withdraw our objection.

9 SPECIAL MASTER VANASKIE: Very well. Thank you.

10 MR. RAE: I think this is another place I can
11 short-cut things a little bit.

12 I'm not sure what we sent to you shows there being an
13 objection on page 98:1 to page 108:18. I know that's one that
14 we withdrew as well.

15 SPECIAL MASTER VANASKIE: Say that again.

16 MR. RAE: Actually, sorry. I'm getting ahead of
17 myself.

18 So what's the next objection you have that we should
19 be discussing?

20 SPECIAL MASTER VANASKIE: I think it's page 99, line
21 1 to 100, page 18.

22 MR. RAE: Yes. So I was saying that this and the
23 objection on page 100, line 21 is the same issue as before
24 with kind of the version of what was submitted to Your Honor,
25 and we've withdrawn that objection.

1 SPECIAL MASTER VANASKIE: All right. Very well. So
2 all of that is coming in?

3 MR. RAE: Correct.

4 SPECIAL MASTER VANASKIE: So are we moving now to
5 page 140, line 16, or are there objections to take up before
6 that?

7 MR. NIGH: I might have 114, line 13 to 17.

8 Is that right, Jacob?

9 MR. RAE: I think that objection was just with
10 respect to completeness and for a counter. My understanding
11 is that you guys are not objecting to our counters in that
12 section, so the 106 objection wouldn't need to be resolved.

13 MR. NIGH: That's right.

14 SPECIAL MASTER VANASKIE: That was my understanding.

15 MR. NIGH: Right. 114, line 18 to 114, line 19, we
16 had no objections to that counter.

17 SPECIAL MASTER VANASKIE: That comes in.

18 Page 115, line 9 to page 115, line 18, there's no
19 objection?

20 MR. NIGH: No objection.

21 SPECIAL MASTER VANASKIE: So that comes in.

22 MR. RAE: And the objection on page 140, lines 16 to
23 22, I think that there was a prior -- this is kind of just
24 like a transcription issue with kind of exchanges of
25 designations that we had had in the past. And I think we had

1 the 106 objection at one point in time, but it's been resolved
2 and we have withdrawn the objection.

3 SPECIAL MASTER VANASKIE: All right. Very well. Are
4 you up to page 142, line 12 to 142, line 15?

5 MR. RAE: Sorry. I spoke over you there. I
6 apologize to Ann Marie.

7 We are at that point. And our objection here is,
8 again, this is the cheap versus cheaper issue that we
9 discussed before and upon which Judge Bumb granted our motion
10 in limine.

11 The question here is, "So you are aware that when
12 Torrent first developed valsartan, they wanted to find a cheap
13 API supplier, right?."

14 And that question is, again, kind of -- the witness
15 isn't sure what email it's referencing in his answer, but that
16 question is misquoting the email in exactly the way that Judge
17 Bumb ruled is not permissible.

18 MR. NIGH: Your Honor, I think that the 142:12 to
19 142:15, we would withdraw that.

20 I just want to make sure as we go forward, because
21 there's not really actually an answer from the witness there.

22 SPECIAL MASTER VANASKIE: I couldn't find the answer.

23 MR. NIGH: In addition to the actual -- you know, so
24 I think that that piece isn't actually important. It's going
25 to be as we go forward.

1 So the one at line 47 we withdraw.

2 SPECIAL MASTER VANASKIE: That's the spreadsheet line
3 47, that objection is withdrawn.

4 MR. NIGH: The testimony withdrawn from pages line
5 142 to 12 to page -- or page 142, lines 12 to 15.

6 SPECIAL MASTER VANASKIE: So now we're to page 142,
7 line 23 to 143, line 3.

8 MR. RAE: Your Honor, this is the answer to the prior
9 question following an objection that was interposed. So I
10 assume that plaintiffs are withdrawing this as well.

11 MR. NIGH: We would be withdrawing page 142 to
12 page -- 142, lines 23 and 24, to page 143, line 1.

13 Line 2 and 3 would be introducing the document.

14 MR. RAE: And I think it's probably helpful to
15 discuss that document in the context of our objections to the
16 testimony about it on page 144.

17 SPECIAL MASTER VANASKIE: Okay.

18 MR. RAE: So we -- our objections here kind of are --
19 this is outside of the scope of the 30(b)(6) testimony, and
20 it's a document from 2006 that this witness doesn't have
21 personal knowledge of.

22 Mr. Nigh laid out a bunch of topics upon which
23 Dr. Jaiswal was designated to testify. Those relate to
24 Torrent's testing of valsartan API. They relate to Torrent's
25 quality unit, to some aspects of regulatory compliance issues.

1 But they do not relate to procurement issues from 2006. And
2 specifically this email is about procurement for -- if you go
3 back and look at the email itself, for domestic production of
4 valsartan, meaning Torrent is an Indian company. Domestic
5 production is discussed in the email. It's for production for
6 the Indian market of valsartan.

7 So not only is this outside the scope of the dep --
8 like, of the 30(b) (6) testimony and a document that
9 Dr. Jaiswal lacks personal knowledge of, but it's -- and long
10 predates his employment at Torrent, it's also irrelevant and
11 prejudicial to be talking about this document in the context
12 of this case, which is about Torrent's use of valsartan API
13 within the US market.

14 MR. NIGH: Your Honor, two issues. One, the India
15 thing is a nonissue. It's the same API that they utilized
16 throughout. And obviously the strategy as to whether or not
17 they were using it for India or the US, it becomes the same
18 issue. They want to secure this API that's 60 percent less
19 expensive to use in their finished products. And ultimately,
20 that's what occurs, and they use that, you know, for all of
21 the products that they market. So to say that it's just the
22 India market is just not true.

23 The second piece is, Jaiswal is offered up, like I
24 said, for nearly every single topic. And one of those topics
25 is their API supplier.

1 And, you know, not just procurement, but, you know,
2 to the -- in terms of looking at the adequacy of the API, you
3 know, all -- he governs -- you know, he is oversight, he is
4 the last stop when it comes to API supplier.

5 And obviously the API supply is what leads to the
6 quality control purity in the finished dose products. And
7 that's one of his main functions is oversight of the API
8 supply. In fact, he's in charge of the people who that's
9 their job, is to go and -- who's to go and secure API supply
10 and to do the audits and things of that nature.

11 That all runs right up to him in his personal
12 capacity. But also there's numerous topics that would speak
13 to his oversight of the API supplier in this 30(b) (6) notice.

14 MR. RAE: Your Honor, we don't dispute that
15 Dr. Jaiswal was -- like, Dr. Jaiswal's department and
16 Dr. Jaiswal's 30(b) (6) topics include Dr. Jaiswal covering
17 what the quality department that he oversees at Torrent does
18 with respect to qualification of the API suppliers, with
19 respect to other API suppliers, with respect to supervision of
20 API suppliers.

21 This email is not and this line of questioning is not
22 about any of those issues. This is about the procurement side
23 of Torrent discussing strategy for how to go out and source
24 API, again, for the Indian market at the stage that falls
25 before the quality department getting in and vetting the API

1 supplier and making sure that they can actually supply the API
2 in a quality way, auditing them, all of the things that
3 Dr. Jaiswal was designated as a 30(b) (6) witness to testify
4 about.

5 This is a precursor issue that's about procurement,
6 not about quality. And it's outside of the scope of his
7 30(b) (6) topic, and it's not something that he has personal
8 knowledge of.

9 MR. NIGH: Your Honor, while the defendant may like
10 to inject that being 60 percent less expensive as a bold
11 statement, we need to find API that's 60 percent less
12 expensive, as they would like to inject and say that has
13 nothing to do with safety. Of course it does. It has an
14 implied reason to do with safety. And we establish that
15 through much of the testimony later thereon.

16 Jaiswal's duty is to oversee and manage API
17 suppliers.

18 One of the things that we also point in terms of the
19 30(b) (6) is to oversee and manage API suppliers.

20 If he's being handcuffed with an extra statement that
21 it has to be 60 percent less expensive but still oversee the
22 API supply, that handcuff -- in terms of his safety, making
23 sure that it's secure, it's adequate, that handcuff needs to
24 be explained through him and through the 30(b) (6) witness on
25 those topics. They go hand in hand.

1 MR. RAE: Your Honor, none of the testimony
2 plaintiffs have designated does what Mr. Nigh suggests.
3 Dr. Jaiswal was consistent throughout his testimony that on
4 quality issues, cost factors have no role on what the quality
5 department does, his responsibility to Torrent, the
6 supervision overseeing of API suppliers.

7 Plaintiffs are trying to inject this idea of, as
8 Mr. Nigh said, handcuffs into the case through implications
9 from documents that -- again, there may be other ways that
10 they can get this document in front of the jury in this case,
11 I'm not foreclosing that possibility, but Dr. Jaiswal, both in
12 his personal capacity and his 30(b)(6) capacity, is not the
13 witness for that.

14 Dr. Jaiswal was not testifying about procurement.
15 The witnesses to get this document in through would be
16 witnesses who are testifying about Torrent's procurement
17 process.

18 MR. NIGH: And, Judge, if the statement is you can
19 only use API supply that is 60 percent more inexpensive, which
20 is exactly what this statement is saying, and what we're going
21 to see in documents later, that they needed to use inexpensive
22 API, we saw it with Kelly Gegenheimer already and the ruling
23 before. If that's their statement, then obviously that limits
24 the API that they're able to select from, which in and of
25 itself would limit quality control, all those issues.

1 That's something that goes to the jury. They can
2 look at that and say, inexplicably, if you have, you know, 100
3 APIs that you have access to, but you can only take the ones
4 that are 60 percent cheaper, so that gives you access to just
5 five out of the 100, of course that's going to limit your
6 options in terms of quality, strength and purity.

7 MR. RAE: Your Honor, I think what Mr. Nigh has said
8 is exactly why this is unduly prejudicial and should not come
9 in.

10 Mr. Nigh suggested that this email indicates that
11 there was a requirement for a second source of API to be
12 60 percent cheaper. That's not what this email says. What
13 this email says is quoted in the question at the top of page
14 145 of the transcript, which we have also objected to, which
15 references "developing a second source with a 60 percent price
16 reduction."

17 It's not a statement that this is a requirement.
18 It's not a statement that this is necessary. What plaintiffs
19 want to use this for and the reason why they want this to come
20 into the case is so that they can make the arguments that
21 Mr. Nigh is making which have no relationship to the facts in
22 evidence in this case.

23 And, again, I want to come back to, there may be a
24 way for them to get this in. We may end up talking about that
25 again later on. But Dr. Jaiswal is not a witness. We don't

1 establish a foundation with him. It's outside the scope of
2 his 30(b) (6) topics. It's outside the scope of his personal
3 knowledge. This is an improper -- this entire line of
4 testimony about this document is improper.

5 MR. NIGH: Your Honor, just because I heard some
6 relevancy arguments there as well, if I can address, because
7 we find this to be highly relevant, and it is connected later
8 up in documents as well.

9 Essentially what happened with Torrent is they were
10 precisely handcuffed. They only used one API supplier. And
11 later we are going to show that it is cheaper Chinese API, in
12 their own words. And what we have is we have Dr. Russ, our
13 expert, who says that's precisely the problem, was that they
14 were limited to just this one API. They didn't have an
15 alternative source.

16 And so they were -- obviously what ended up happening
17 thereafter is it allowed ZHP to call the shots. They had
18 nobody else to go to.

19 So when it comes to this cheaper/inexpensive, that
20 all lays its way out all the way through to our own expert who
21 ultimately looks at this and reflects on the same thing, that
22 they only had one API supplier when it was all said and done.
23 I understand this email says an alternative, but what we
24 actually see later thereafter, one API supplier for the entire
25 international market, and it just so happens to be the one

1 that would be more than 60 percent inexpensive.

2 MR. RAE: Your Honor, I think you've heard our
3 arguments at this point.

4 SPECIAL MASTER VANASKIE: I have. And I'll give you
5 my ruling. And that is that the objections are overruled.
6 The testimony is admissible.

7 I want the record to be clear that I'm talking about
8 the testimony that covers pages 146, starting at line 8, down
9 to page 175, line 7, I believe.

10 MR. RAE: Your Honor, if I may, I think what we were
11 just discussing was the deposition designations that we had
12 objected to from page 144 -- or, actually, I think it starts
13 earlier than that, from 142 --

14 SPECIAL MASTER VANASKIE: You are right.

15 MR. RAE: -- where the document is introduced -- I'm
16 sorry, 143, line 2 to 146, line 17.

17 And then on page 147, plaintiffs transition to asking
18 about a different document, which Your Honor may have a
19 similar ruling on. We have similar objections to this, again,
20 being an email about procurement that doesn't have to do with
21 quality control.

22 And I may be understanding Your Honor to say that
23 you're going to be ruling in the same way about these issues,
24 but --

25 SPECIAL MASTER VANASKIE: Yes, I am going to rule in

1 a similar way. It seemed to me to be a continuation of that
2 line of questioning dealing with sourcing the API and using a
3 supplier that was less expensive.

4 And I guess to make that clear, I find that to be
5 highly relevant and not barred under Rule 403 principles. In
6 terms of this witness's foundation, he's a 30(b)(6) deponent.
7 And it seems to me he's an appropriate person to pose these
8 questions to.

9 So we can go excerpt by excerpt, but I thought I'd
10 short-circuit that a little bit by treating them all together.

11 MR. RAE: No, Your Honor. Understood.

12 I think with respect to the testimony from lines
13 166 -- I'm not going to kind of -- just the broad range, like,
14 beginning on page 166, line 8 through 175, line 17, there's a
15 number of lines of testimony that we objected to on the basis
16 of foundation there.

17 Those relate to other than we don't have the same
18 scope objections that I discussed before. That's clearly
19 within the scope of the 30(b)(6) topics.

20 We also are not making kind of the 401 and 403
21 objections, but we still have a foundation objection, because
22 the witness testified that he had never seen that email
23 before.

24 I think it's -- we would request -- I don't think
25 actually --

1 SPECIAL MASTER VANASKIE: Let's go through this.

2 This is different.

3 MR. RAE: All right.

4 MR. NIGH: Yeah, Your Honor, if I can, I just want to
5 clean up exactly what the prior ruling is for.

6 My understanding is it's 143, line 2 -- all of the
7 designated testimony from line 143 -- or page 143, line 2.

8 And where did it end? That's what I'm trying to find
9 here.

10 Is it 152, line 23? I don't think that there's any
11 objection --

12 SPECIAL MASTER VANASKIE: That's what I had: 152,
13 line 23.

14 MR. NIGH: Is that right, Jacob, in your belief?

15 MR. RAE: Yes.

16 MR. NIGH: Okay.

17 MR. RAE: Then I think the next batch of testimony
18 which relates to the next document is from 166, line 8 to 175,
19 line 17.

20 As I said, our primary objection is a foundation
21 objection.

22 The counter that we designated from 173, line 17 to
23 174, line 9, identifying kind of the witness indicating that
24 he had not seen this email before is -- shows the basis for
25 that objection and I think would also -- in fairness should be

1 coming in front of the jury to the extent Your Honor is going
2 to let in this testimony.

3 SPECIAL MASTER VANASKIE: Okay. So this is 166, line
4 8?

5 MR. NIGH: Your Honor --

6 SPECIAL MASTER VANASKIE: Go ahead. Help me out
7 here.

8 MR. NIGH: Yeah, if I can.

9 This is one of the more puzzling objections to me,
10 because, as we established before, the role of oversight of
11 the API supplier, you know, it runs right up to Jaiswal. He's
12 being put up as the 30(b)(6) witness.

13 And so for him to have not seen an email where --
14 Jenny Yang is the inspector who goes to ZHP's facility and
15 comes back after that -- having that inspection and lays out
16 in an email, very summary, stating that they don't
17 understand -- if I can get the quote here real quick.

18 In other words, he comes back from the audit. He
19 says all sorts of problems in his summary email. The people
20 from this manufacturer is too much protective of their system
21 is one of the statements. Another one says something like
22 they don't understand safety. They don't understand
23 degradation.

24 So -- and I can find those here. But they're very
25 troubling statements from Jenny Yang coming right back, fresh

1 off of the inspection.

2 So for the person who is being put up as the
3 oversight of API supplier to not have ever seen that email in
4 and of itself is very odd, because he should have had a duty
5 to look at all the information related to oversight of API
6 before he even took the deposition. But he didn't, and so
7 maybe he's speaking on behalf of Torrent. But nobody saw that
8 email.

9 But on top of that, he also is the supervisor of the
10 API supplies. And quintessential to that is that Torrent has
11 a duty to inspect. It's not just check off the boxes that
12 they did an inspection, it is that they actually follow up on
13 the problems that they see in the inspection.

14 And so what we're going to see is that this email is
15 sent, and it drops off the face of the planet after that. It
16 doesn't show up in the formal CAPA. And obviously, it didn't
17 even -- you know, for whatever reason, Jaiswal doesn't even
18 know about it. It's extremely relevant.

19 MR. RAE: Your Honor, I don't think it's relevant to
20 kind of the deposition objections we have here, but what
21 Mr. Nigh said is not true as a matter of the record. There is
22 follow-up correspondence from Dr. Yang indicating that she
23 followed up with ZHP, that ZHP had closed out the issues, that
24 they had satisfied CAPA and that her audit was complete.

25 This is kind of a normal back-and-forth process of

1 audits: Identify issues. Those issues get resolved. Things
2 move on.

3 But, again, I don't think that's something that we
4 have to be hashing out here. This is not a trial on the
5 merits of the case here. This is about our foundation
6 objection to this line of testimony.

7 And as I said, I think Your Honor has essentially
8 already ruled that you are going to let this in was my
9 understanding.

10 SPECIAL MASTER VANASKIE: Yes.

11 MR. RAE: So our main ask was that our
12 counter-designation also come in.

13 SPECIAL MASTER VANASKIE: Your counter-designation at
14 page 173, line 17 to 174, line 9?

15 MR. RAE: Correct.

16 MR. NIGH: Your Honor, if I could have one second to
17 look at those real quick.

18 MR. RAE: Just to correct it, it probably should be
19 173, line 20, because the beginning of that -- and I'm going
20 to modify it now on the fly because the beginning of that
21 looks like it is Ms. Brancato's foundation objection, which
22 should not be getting designated.

23 SPECIAL MASTER VANASKIE: Right.

24 MR. NIGH: Your Honor, we have no objection to that
25 counter. I will withdraw it. I think it's actually good for

1 us.

2 SPECIAL MASTER VANASKIE: Okay. So the counter will
3 come in from page 173, line 20 to 174, line 9.

4 Correct, Jacob?

5 MR. RAE: Correct.

6 SPECIAL MASTER VANASKIE: What's our next contested
7 designation?

8 MR. NIGH: I guess I want to be clear that Your
9 Honor's prior ruling, Jacob understood his objections to be
10 overruled, runs from page 166, line 8, all the way through
11 page 175, line 17.

12 MR. RAE: That was my understanding, yes.

13 MR. NIGH: Okay.

14 SPECIAL MASTER VANASKIE: Yes, that is correct.

15 MR. NIGH: I think the next one is a counter at
16 182 -- or, sorry, it's -- counter to page 182:12 to 18. And
17 they're trying to include pages 191, seven pages later, 11 to
18 15, which we don't see as responsive. But on top of that,
19 it's not a response to any question, even at 191. It's just a
20 talking point.

21 MR. RAE: Your Honor, again, the counter here runs
22 from 191:11 to 193:4. It's the question and answer in that
23 segment with just kind of a brief cutout from 16 -- 191, lines
24 16 to 19, where there was an interposed objection and kind of
25 a brief cutoff of the beginning of the witness's answer that

1 got cut off by that objection before the witness began to
2 answer the question in earnest.

3 MR. NIGH: I guess I can't even tell what it's
4 responsive to, anything that we've designated.

5 It looks like they should just do an affirmative
6 designation for this one.

7 MR. RAE: So, Your Honor, this is a line of
8 questioning running from page 184 through -- certainly through
9 at least page 193, where plaintiffs are asking questions about
10 the genotoxic declarations that came from ZHP to Torrent.

11 That line -- the counter that we have is directly
12 relevant to that line of questioning about genotoxic
13 declarations and genotoxic impurity questions. It's a
14 question that plaintiffs themselves thought was relevant to
15 kind of the general topics that they were asking about, which
16 is why they asked it in their deposition.

17 We think that in fairness it needs to be read along
18 with these questions, because the -- particularly the question
19 on line -- on page 193, line 17 to 21, about how Torrent, as a
20 finished dose manufacturer, has a duty to follow industry
21 standards regarding genotoxic impurities.

22 The counter-designation that we have explains what
23 those industry standards are with respect to genotoxic
24 impurity testing.

25 SPECIAL MASTER VANASKIE: Yeah, I think the

1 counter-designation does come in.

2 MR. RAE: Thank you, Your Honor.

3 MR. NIGH: Your Honor, if I may, I don't see how
4 that's responsive to 17 to 21. I think they are just -- at
5 193. I didn't even know what it was responsive to.

6 But the information here is not responsive to that
7 Torrent has a duty to follow industry standards regarding
8 genotoxic impurities. This is talking about, you know, DMF,
9 ANDA.

10 You know, to the extent they want to try to fit it in
11 to say that is their duty -- that's not what it says. It's a
12 broad, long, run-on statement that isn't even responsive to
13 197, line -- or 193, line 17 to 21.

14 SPECIAL MASTER VANASKIE: I do think it's permissible
15 for Torrent to designate this part of the testimony. And I
16 don't see how you're prejudiced by it.

17 MR. NIGH: Yes, Your Honor.

18 SPECIAL MASTER VANASKIE: Go ahead.

19 MR. RAE: I'm going to jump in, because I think we
20 have a couple more objections that we withdrew that I can kind
21 of short-cut us.

22 You're probably looking at -- there's no current
23 objection on page 210, lines 3 to 9. And there's no objection
24 on page 251, line 9 to 22.

25 The next objection is page 252, line 4 to 17.

1 And, Your Honor, our objection here is that it's both
2 a foundation question and a form and argumentative nature of
3 the question objection. There's an outside the scope
4 objection, but I'm going to assume that Your Honor is going to
5 rule in line with your previous rulings with respect to the
6 scope issues, so I want to focus on the prejudice,
7 argumentative nature of the question, 602 issue.

8 SPECIAL MASTER VANASKIE: Okay.

9 MR. RAE: The issue here is -- the question is: "So
10 the decision to put the product back on the market had nothing
11 to do with the money y'all would lose in the meantime?"

12 And that question implies that there is evidence
13 indicating that the decision had to do with Torrent losing
14 money. And that's not testimony that's been established.
15 That's not evidence in the record. In fact, the testimony
16 that plaintiffs themselves have designated on page 252, just
17 before this question, says: The decision-making process sits
18 with Dr. Jaiswal. Dr. Jaiswal says, "I'm holding those
19 decisions. I never see -- and I have indicated every time we
20 have this discussion, I was not knowing that," and that he was
21 not knowing that there was any discussion about supplier
22 issues or price at the time that he was personally responsible
23 for making the decisions about what Torrent could do from a
24 quality perspective during, at this point, the summer of --
25 June and July of 2018.

1 Dr. Jaiswal goes on, "But this is a purely technical
2 call based upon the assessment of the database, based on the
3 assessment of the DMF holder, what declaration they have
4 given."

5 The question implies that the jury should be thinking
6 something entirely different from what the evidence should
7 show, something that's not supported in the record, and it
8 would be incredibly prejudicial to let the jury hear this
9 question that lacks a foundation and is argumentative.

10 SPECIAL MASTER VANASKIE: Daniel?

11 MR. NIGH: Your Honor, to suggest that this isn't
12 supported in the record -- I think it's important to do the
13 back of what has been displayed thus far and what we're also
14 going to lay with other witnesses as well, but it's also in
15 this deposition transcript.

16 Essentially what occurred is Dawn Chitty -- who is a
17 subordinate to Jaiswal; she reports to Jaiswal. And she's the
18 person in -- one of the people in charge of quality, who is
19 constantly ringing the drum that we've got to test this
20 product to see if our own product has NDMA. We can't just
21 rely on ZHP's statement that there is no genotoxins in it, and
22 for likely good reasons, because ZHP has been wrong for them
23 before, which is that they sold new process in Europe. They
24 relied on that note, genotoxic statement. And of course they
25 found out that their new process clearly had genotoxins. They

1 knew at the time that this was happening.

2 So to put all that in respect, she's saying, we've
3 got to test, we've got to test, we've got to make sure there's
4 no genotoxins in this. And the very next day, or actually the
5 same day that she says we've got to test -- and I say "same
6 day" because there's a difference in the time zones, she's in
7 the US and India.

8 But the same day it's happening, their CEO goes
9 around, takes her off the list, and shows how much do we have
10 in supply, what are we going to lose in terms of if we fail to
11 supply product on time, what are going to be the penalties
12 that happen because of that. That's all in the emails that
13 we're presenting to him.

14 So we're asking him, this decision to put the product
15 back on the market, was that driven in any way due to finances
16 as far as you're concerned?

17 And that's the question. It's a fair question to the
18 person in charge of quality and safety.

19 SPECIAL MASTER VANASKIE: I'm not sure it's a fair
20 question of that person.

21 MR. RAE: Your Honor, just to be clear, the question
22 that Mr. Nigh just asked, that's the question that's at 251,
23 lines 20 to 22 of the transcript. We haven't objected to that
24 question. That question and the answer to it is coming in.

25 We're objecting to the subsequent question that

1 follows it, that implies that the witness's answer, that it's
2 an argumentative question that's framed in a way that implies
3 to the jury that counsel thinks that the witness is lying.
4 There's no foundation for that assumption.

5 This witness was not on that email chain, and he's
6 testifying to the process that he engaged in in overseeing
7 Torrent's quality control process.

8 So again, like, the facts here are coming in. The
9 testimony from 251:20 to 22, 252:4 to 13, that's coming in.
10 It's the next question that we're objecting to.

11 SPECIAL MASTER VANASKIE: You're objecting to the
12 question, "So the decision to put the product back on the
13 market had nothing to do with the money y'all would lose in
14 the meantime?"

15 MR. RAE: Correct. And we are not objecting to
16 "Torrent was ready to put its product back on the market so it
17 didn't continue to lose money, correct?"

18 I think the difference between those two questions is
19 obvious. And the reasons why we're objecting to one but not
20 the other is also, I would think, obvious.

21 MR. NIGH: Judge, one brief statement, Your Honor, is
22 that -- and I don't think your ruling will change on this, but
23 just to keep in mind, obviously it's a 30(b) (6) witness who is
24 in charge of quality and safety. So the fact of whether or
25 not he was personally on the email is irrelevant to that

1 issue.

2 SPECIAL MASTER VANASKIE: And I'm going to sustain
3 this objection.

4 MR. NIGH: Okay.

5 MR. RAE: Thank you, Your Honor.

6 SPECIAL MASTER VANASKIE: What do we have next?

7 We're going to go for about 15 more minutes and then take a
8 break.

9 MR. RAE: I think the next objection I have is on
10 page 257, line 9 to 17.

11 MR. NIGH: Is there a counter to 254:3 to 6?

12 MR. RAE: I believe we had agreed -- was it yesterday
13 when we spoke that you guys were going to designate 254:3 to
14 11, that we were going to drop our counter, that you were
15 going to drop the next question, and then we were going to
16 pick up at 252, line 2 to 6, and that that had resolved
17 everything in this section.

18 MR. NIGH: We agree with that. That's right.

19 SPECIAL MASTER VANASKIE: All right.

20 MR. NIGH: So yes, 257, line 9 through 17.

21 MR. RAE: And, Your Honor, I think this one is pretty
22 straightforward. There's a question here. There's no
23 designated answer. It's just attorney commentary that's being
24 apparently kind of designated and being put in front of the
25 jury as part of the record.

1 MR. NIGH: Your Honor, it actually goes through --
2 this is another one of those sort of -- you got to read them
3 together. It goes through to the next one and then the next
4 one after that, you know. So it's all together as one.

5 Because his answer to it later is well, did I see,
6 blah, blah, blah. And then ultimately we point him to where
7 it really is, and then he starts to answer.

8 So the 9 to 17 is the beginning of the question and
9 answers that go back in terms of the next ones following,
10 258:4 to 258:19.

11 MR. RAE: I think the only thing I would say then is
12 that the question on 258:4 to 5 seems unnecessary to me, if
13 the position you're taking is that the answer beginning at
14 258:6 is an answer to the question, 257:9 to 17.

15 MR. NIGH: I think it's -- it just flows from there.
16 And in terms of the flow, I think it makes more sense to have
17 that designation that way.

18 SPECIAL MASTER VANASKIE: Yeah. It just seems to
19 flow better that way as well, so we'll leave that in.

20 MR. RAE: Okay.

21 MR. NIGH: And I am not really sure where objections
22 happen after that, because we've got lacks foundation, and
23 these obviously -- I don't know where the next objection is
24 after that. So maybe I'll leave that to Jacob.

25 MR. RAE: So the next objection is to the question

1 and answer that kind of -- leaving aside kind of omitted
2 portions for objections is 258:16 to the end of the page, to
3 line 24 on that page.

4 And I think this is a similar objection to the one
5 that Your Honor sustained a moment ago. We're not objecting
6 to the questions about the content of the email. We're not
7 objecting to kind of the questions about the decision-making
8 process, but we're objecting to this question as argumentative
9 and prejudicial and lacking foundation in kind of implying
10 that and suggesting that Torrent --

11 MR. NIGH: Your Honor, I don't think it's related at
12 all.

13 SPECIAL MASTER VANASKIE: The question is --

14 MR. NIGH: I could see some relation, but
15 essentially, he's part of this email -- he remembers this
16 conversation. He's part of it.

17 So the fact that the failure to supply and pay
18 penalties, pay supply penalties, he's part of this decision
19 now. It's not like he's been left off of it. And he
20 remembers it, he's answering it, he knows about it.
21 Obviously, this all factored into even as his role in charge
22 of quality and safety.

23 SPECIAL MASTER VANASKIE: Well, his answer is,
24 "Maybe. I'm not really sure. But yes, it's been written in
25 the mail."

1 MR. NIGH: And then further down you can see he
2 remembers the conversation. "This is the assessment of the
3 market situation they have given."

4 Yes, it's true. It was given to him.

5 MR. RAE: And, again, we're not objecting to the
6 question about the content of the email. We're not objecting
7 to the questioning on line 259 about whether or not
8 Dr. Jaiswal remembers the conversation or kind of him
9 affirming it. We're only objecting to this question from 16
10 to 24 on page 258.

11 SPECIAL MASTER VANASKIE: It's not all that clear.
12 But I will sustain the objection, primarily because the
13 objection is foundation. The witness says, "I'm not really
14 sure. But yes, it's been written in the mail." You get down,
15 you get the testimony in about remembering the conversation.

16 But I will sustain the objection.

17 MR. NIGH: So 259:2 through 15 comes in but 258:16 to
18 24 is out?

19 SPECIAL MASTER VANASKIE: Correct.

20 MR. NIGH: I understand, Your Honor.

21 SPECIAL MASTER VANASKIE: What do we have next?

22 MR. RAE: Next is 261, line 19 to 262, line 5 is the
23 question and answer that our objection is to.

24 And I think this is, again, the same issue that we
25 were just discussing, and, again, kind of there's a foundation

1 here. The witness's answer demonstrates that the witness is
2 being confused by this. And similarly to the other issues as
3 this kind of comes back in 262, lines 7 kind of forward, we're
4 not objecting to that testimony about where the witness
5 actually does remember things he's grounded and where there
6 are kind of answers to the questions.

7 MR. NIGH: I guess I don't know where the objection
8 starts and ends on this one.

9 MR. RAE: The objection is just the first question at
10 the bottom of 261 in this kind of set of designations. So
11 261, line 19 to 262, line 5.

12 MR. NIGH: Yes.

13 SPECIAL MASTER VANASKIE: I'll sustain the objection.
14 Go ahead.

15 MR. NIGH: Your Honor, the relevancy in part is
16 because he is an employee in India. This actually ties up
17 that it's going back on the market on the same day. It ties
18 up that it is the same day from the day that -- that Chitty is
19 raising the issues. He's in India, and so it helps to
20 establish this time difference that we just talked about. And
21 that's why it's important to have that same day it happened.

22 And he answers both of those questions later. But he
23 doesn't say same day. He answers the day and then he answers
24 the other. But the importance is the date is the same day.

25 SPECIAL MASTER VANASKIE: Well, why isn't it

1 sufficient, Daniel, to just start at page 262, line 7 and go
2 on from there?

3 "I remember on which date FDA has given me clearance
4 to go back on the market.

5 "What day was that?

6 "That date, I think it was -- it is on the 18th of
7 July."

8 Why isn't that sufficient?

9 MR. NIGH: I see. I hadn't seen down to 262:24, and
10 we did designate that which does say "Same day y'all get the
11 drugs put back on the market?" I think that is sufficient.

12 SPECIAL MASTER VANASKIE: Okay. So to be clear, I've
13 sustained the objection at page 262, lines 2 and 3 and the
14 answer that would have come after that at lines 4 and 5. All
15 right?

16 MR. NIGH: And Judge, I think it's pages 261, line 19
17 to 262, line 5.

18 SPECIAL MASTER VANASKIE: Line 5, yeah. I think so
19 too.

20 MR. NIGH: That's taken out.

21 SPECIAL MASTER VANASKIE: That's taken out.

22 MR. NIGH: But then 262, line 7, to page 263, line 3
23 comes in.

24 SPECIAL MASTER VANASKIE: Yeah.

25 MR. NIGH: Okay.

1 SPECIAL MASTER VANASKIE: All right. What do we have
2 next?

3 MR. RAE: Next I think there's a plaintiffs'
4 objection to our counter-designation at -- beginning at 264,
5 line 17. And then the counter-designation runs again with a
6 little bit of material that's been left out because it's kind
7 of cross-chatter to 266, line 5.

8 SPECIAL MASTER VANASKIE: Okay.

9 MR. RAE: I don't know if the best way to proceed is
10 for me to explain kind of the reasoning behind our counter or
11 for Mr. Nigh to explain his objection to it.

12 SPECIAL MASTER VANASKIE: Let me just make sure I'm
13 on the right question and objection.

14 The question starts on page 264, line 17. "Okay. So
15 Dawn Chitty -- Dawn Chitty thinks you guys need to figure out
16 the testing method to head off potential liability, right?"

17 And there's objection to foundation.

18 Is that where we're at?

19 MR. RAE: Yes.

20 MR. NIGH: Just looking at it, it's actually just
21 things that, you know, they'd like to interject that aren't
22 responsive to any of the questions. So we would say that any
23 of this should be designated either in an affirmative or they
24 should put Jaiswal on the stand. These aren't the questions
25 being asked.

1 MR. RAE: Your Honor, frankly, the question that
2 immediately precedes this is about what Dawn Chitty wrote in
3 this email. And the counter-designation is the questions and
4 answers that explain what Dr. Jaiswal understood Dawn Chitty
5 to be communicating in the language that she wrote, that they
6 ask Dr. Jaiswal to acknowledge she wrote in the prior
7 question. And from 264, line 6 to 264, line 16.

8 And so we think that this is just a straightforward
9 issue of fairness and completeness, to have the testimony from
10 Dr. Jaiswal explaining the language in this email and what he
11 understood from it, alongside the designation from plaintiffs
12 asking Dr. Jaiswal to confirm that that's what Dawn Chitty
13 wrote to him.

14 SPECIAL MASTER VANASKIE: Yeah. I think this comes
15 in. I can't find a reason to exclude it.

16 MR. NIGH: Your Honor, if that's going to come in, we
17 would ask that it runs all the way to line 12 of page 266.

18 SPECIAL MASTER VANASKIE: Yes. I agree.

19 MR. RAE: I'm not going to bog us down with any
20 objections to that.

21 SPECIAL MASTER VANASKIE: Okay. All right. Why
22 don't we take a break now.

23 Ann Marie, is it all right if we take an hour break?

24 Okay. So we'll take a break until 1:15. We'll see
25 you back then.

1 MR. NIGH: Thank you, Your Honor.

2 MR. RAE: Thank you, Your Honor.

3 (Recess at 12:15 p.m. until 1:20 p.m.)

4 SPECIAL MASTER VANASKIE: We're continuing our
5 conference on deposition designations. We're still working on
6 Dr. Jaiswal.

7 And where are we picking up?

8 MR. RAE: We're picking up at the question and answer
9 on page 305, line 15 and then running through page 306, line
10 9. There's sort of two blocks of testimony designated for the
11 question and the answer.

12 SPECIAL MASTER VANASKIE: All right. Let me pull
13 that up.

14 So what's the argument on this?

15 MR. RAE: Your Honor, the argument here is -- there's
16 two issues here. One is that Dr. Jaiswal -- this is a
17 question about the regulatory process for submitting -- for US
18 regulatory submissions. And Dr. Jaiswal was not designated as
19 a 30(b) (6) on that topic, so this is outside the scope of his
20 30(b) (6) testimony.

21 And then the second issue is really with the premise
22 of this question, the "when you become aware of some quality
23 implication," that that hypothetical formation of the question
24 imply -- will imply to the jury that Torrent did become aware
25 of some quality implication at some point in time. And that

1 premise lacks foundation, and it's unfairly prejudicial to ask
2 a question framed in that way.

3 SPECIAL MASTER VANASKIE: Daniel?

4 MR. NIGH: First off, I'm kind of stunned by the
5 30(b)(6). I don't know how far I need to go into that.

6 But he's the head of -- he's the main analytical
7 chemist in the company. He's the head of testing, you know.
8 And it's almost like the defendant wants to be able to put
9 everything in a box and say, oh, this is the regulatory box.
10 He knows no idea -- he doesn't know how to deal with
11 regulatory.

12 Of course he does. He knows that if he needs to get
13 testing done, this is the way he goes about it, and he sends
14 off and says I need to have this certain test to find this
15 certain thing, add this to the ANDA, get this done.

16 And his answer is precisely that, he knows that it
17 doesn't -- he knows the regulatory actions that have to occur
18 downstream for him to be able to do his job. And so that's
19 clear.

20 Second, the idea of the sort of questions on -- of
21 course there's a foundation for that. What we see is the
22 finished dose manufacturer, Novartis, when they find that
23 there is an unknown peak, they figure out how to test for the
24 unknown peak, and then they ultimately find out that there's
25 NDMA.

1 And one of the defenses here by the other side is,
2 well, we didn't have it in our ANDA, it didn't allow us to
3 test this certain way, so we couldn't find it.

4 Well, this just clearly knocks that out. Of course
5 you can. You go ahead and you ask for this testing and you
6 can get it approved.

7 MR. RAE: Your Honor, just to respond briefly on the
8 30(b) (6) issue. I think that's actually an important issue
9 here, because I heard Mr. Nigh respond to the lot of ways in
10 which this witness has personal knowledge on -- like,
11 potentially has personal knowledge here. That's not the basis
12 of our objection.

13 But I think it's also important to remember that this
14 is a witness that plaintiffs are being allowed to play
15 deposition designations from this witness as part of their
16 case-in-chief, even though he's going to be available live to
17 testify at trial.

18 And the primary reason that they argue that they
19 should be able to do that is because 30(b) (6) testimony
20 qualifies as an admission under the Federal Rules of Evidence,
21 but testimony that's being given by a witness in his personal
22 capacity doesn't. And Dr. Jaiswal is going to be appearing
23 live at trial. He's been available live. He was never
24 unavailable to plaintiffs. We offered to make him available
25 during plaintiffs' case-in-chief.

1 And so the elaboration on how Dr. Jaiswal has
2 personal knowledge on this issue is very different from this
3 being outside scope of his 30(b) (6) testimony and therefore
4 being testimony that should be getting presented to the jury
5 live.

6 MR. NIGH: Your Honor, briefly --

7 SPECIAL MASTER VANASKIE: What are you trying to
8 establish here, Daniel?

9 MR. NIGH: Your Honor, briefly, I'm looking at the
10 30(b) (6) notice. And it's kind of appalling to me that's
11 still the objection, because there are at least 20 topics that
12 this would be relevant towards.

13 The idea that the -- they're not limited in terms of
14 the testing that can be performed, because all they have to do
15 is be able to ask for this sort of testing, and they will get
16 it.

17 And so numerous topics speak to this, from testing of
18 valsartan API in finished dose that's in the product and it's
19 talking about chromatograms, mass spectrometry. It's all
20 throughout. That's what we're suggesting.

21 You didn't have the actual -- you may not have had
22 the actual test that was in the ANDA approved at the time, but
23 you could have just asked for it.

24 And so he's going to pair his knowledge of the test
25 that he needs with the -- and I don't just mean his knowledge.

1 I mean the 30(b) (6) topics knowledge along with the way in
2 which to ask for it.

3 SPECIAL MASTER VANASKIE: So to the extent the
4 objection is that this is outside the scope of the 30(b) (6)
5 notice, I would overrule that.

6 Is there any other basis for objecting to this
7 testimony, Jacob?

8 MR. RAE: Yeah, Your Honor. As I said at the
9 beginning, the premise of this question, when you become aware
10 of some quality implication, will imply to the jury in asking
11 this question that Torrent became aware of some quality
12 implication, and there's no foundation laid for that premise
13 as a hypothetical to found this question on.

14 SPECIAL MASTER VANASKIE: I'll overrule that
15 objection as well.

16 Anything else on this?

17 MR. RAE: No, Your Honor.

18 SPECIAL MASTER VANASKIE: All right. What's our next
19 one?

20 MR. NIGH: I believe it's defendant's counter 314:5
21 to 315:6 and then 316:9 to 317:21. And they both kind of fall
22 under the same bucket.

23 Is that right, are those the next two, Jacob?

24 MR. RAE: Yes. I would agree that they fall under
25 the same bucket as well.

1 MR. NIGH: So essentially let me explain this a
2 little bit further, which is we had a similar issue already in
3 191:11 to 193:4, where the defendants want to -- it's one of
4 their talking points. Every time they ask a question, you
5 know, at some point they want to stick in and say, well,
6 there's an open part of the DMF where we're able to see
7 certain activity of what's going on in the DMF and then
8 there's a closed part of the DMF that we can't see certain
9 things.

10 And so that's exactly what's happened here. You will
11 notice, just as it was in 191, it's interjected pages later
12 from anything that we designate, but at least 191 had some
13 semblance of what it went to. Here, we're just -- I mean,
14 it's almost getting to the point where I could ask him what he
15 had for breakfast and he would say, well, you know, there's an
16 open part of the DMF, and the open part of the DMF allows me
17 to do blah, blah, blah, but the closed part of the DMF doesn't
18 allow me to blah, blah, blah.

19 And that's what we're going to see, this running
20 theme all throughout where they just want to stick in -- and
21 there's a way they should do this. And that is, they said
22 they're going to call Jaiswal live. When they call Jaiswal
23 live, he can say everything he wants to his heart's desire
24 about the open part of the DMF, the closed part of the DMF.
25 And I will tell you and assure you, at that time we will come

1 prepared with a cross-examination for that piece. But that
2 has nothing to do with anything that I questioned before and
3 after that we've designated.

4 The other part of this question, as we've said
5 multiple times, that if we de-designate, then the counter
6 should go away; but I don't even know what we would
7 de-designate for this counter to go away because it's not
8 responsive to anything we've designated even remotely within
9 its pages. It's like eight pages later, either before or
10 after our questions.

11 MR. RAE: Your Honor, my apologies.

12 SPECIAL MASTER VANASKIE: Go ahead.

13 MR. RAE: To clarify, there's a lengthy line of
14 questioning beginning at page 325 of Dr. Jaiswal about the
15 contents of ZHP's DMF. The chemistry -- the synthetic
16 chemistry, the chemistry on paper that one could do if one had
17 access to that full DMF, and the conclusions that one could
18 potentially draw from having that access, knowing the
19 information in that DMF, the full information in that DMF and
20 conducting synthetic chemistry based on that.

21 Our counter directly relates to -- and in fairness,
22 it needs to be played alongside that to make it clear to the
23 jury that this line of questioning that we're not objecting to
24 about what Dr. Jaiswal is testifying you could know based on
25 the contents of the DMF is information that Torrent did not

1 have.

2 And that's -- from a fairness perspective, I hear
3 Mr. Nigh saying Dr. Jaiswal can come on direct weeks after
4 this video is played when the case turns over to defendants
5 and we're presenting our defense case, we'll be able to
6 provide that context. But, frankly, Your Honor, that's not
7 sufficient, because if the jury sits with the implication that
8 this line of questioning relates to information that Torrent
9 would have had at the time, they're going to be sitting for
10 days, if not weeks, without the context of the fact that
11 Torrent didn't actually have this information. So we think
12 it's critical that that testimony be played at the same time
13 so that the jury can hear the full context of the testimony
14 that plaintiffs are designating.

15 MR. NIGH: And, Your Honor, if I can respond briefly,
16 which is -- you know, a big part of this problem is we're not
17 asking him in any of those questions -- none of them, it's
18 pains -- it's obvious that I purposely am not asking him in
19 any of those questions, did Torrent have access to the open
20 part or the closed part of the DMF. That's not asked.

21 It's simply asked if you had the full chemical
22 process, could you do X, Y and Z. That's it. It's not asked,
23 did you have the open part, did you have the closed part,
24 what's your analysis on open and closed; because I can
25 guarantee the defendants, we have a lengthy cross-examination

1 on that topic as to what they had access to and did not.

2 But for them to be able to interject that in here and
3 keep saying we didn't have access when that's not my
4 questions, because they do have access to a lot of things
5 they're not talking about. But I am not asking about that
6 here.

7 MR. RAE: Your Honor, if I may.

8 SPECIAL MASTER VANASKIE: Go ahead, Jacob.

9 MR. RAE: This comes back to the fairness issue,
10 which is I hear Mr. Nigh saying they're not asking these
11 questions, but the questions were asked in Dr. Jaiswal's
12 deposition. The questions were answered in his deposition.

13 And the issue here is that they're using video
14 designations for a witness who is available to them live to
15 cut up the testimony that they're going to play for the
16 witness and to deprive us of the ability to cross-examine
17 Dr. Jaiswal directly following that examination.

18 And because we're being deprived of that opportunity
19 to redirect or cross or whatever term we want to use for their
20 presentation of their witness, it's imperative that we have
21 the fair opportunity to play fairly limited
22 counter-designations that correct the record on areas where
23 plaintiffs aren't asking the questions that would provide the
24 necessary context to the jury about what they're hearing from
25 the testimony the plaintiffs have designated.

1 SPECIAL MASTER VANASKIE: Please tell me the specific
2 page and lines of testimony that you want to play, Jacob.

3 MR. RAE: The pages and lines that we want to play
4 are starting at page 314, line 5 to 315, line 6. And that's
5 primarily discussing the fact that this synthetic chemistry
6 assessment that plaintiffs are later going to ask about is
7 something that's conducted by the DMF holder, not by Torrent.

8 And then from 316, line 9 to 317, line 21, which I
9 think covers generally kind of the same sort of issues and
10 also just -- generally covers kind of the same sort of issues
11 and further contextualizes that information.

12 MR. NIGH: Your Honor, if I may, just to go a little
13 bit further.

14 First off, the purpose of direct examination in their
15 case, if they really, truly want to say to correct the record,
16 that's the purpose.

17 But second, they've already gotten to inject this
18 information into page 191, line 11 to 193, line 4. And what
19 we're going to see is over and over again -- like I said, we
20 can ask him what he had for breakfast, and they're going to
21 start injecting, well, there's an open part of the DMF and a
22 closed part of DMF, or any way that they can kind of remotely
23 make it related to the question. And it's going to happen
24 over and over and over again. To be fair to us, it's not what
25 we're asking.

1 MR. RAE: Your Honor, I think the issue is that they
2 come back to similar lines of questioning over and over and
3 over again. And so in fairness, the jury should be hearing
4 the context related to that as it comes up, not kind of in --
5 and that's kind of the purpose of our counters.

6 And, again, if this testimony were happening live,
7 plaintiffs would obviously be entitled to present their
8 questions to limit the scope, and then we would come back
9 following that and present our testimony, ask our questions.

10 That's not the way that plaintiffs are choosing to
11 pursue their case. They're choosing to present their case via
12 video testimony. And I think it's clear on the record of our
13 counter-designations here that we're not asking to play two
14 hours of counter-designations here. I haven't added them up,
15 but my guess would be the total length of our
16 counter-designations to their over two hours of designations
17 of testimony is probably somewhere in the range of ten
18 minutes.

19 SPECIAL MASTER VANASKIE: I think in fairness to you,
20 you should be able to ask those questions to be considered at
21 the time that the testimony designated by plaintiffs is
22 presented, so I will allow that to happen.

23 We're talking about the testimony on page 314, from
24 line 5 through page 315, line 6; and page 316, line 9 through
25 page 317, line 21.

1 MR. NIGH: Your Honor, if I may, what is that a
2 counter to? Because we should be able to examine that and see
3 whether or not we even want that original testimony in the
4 first place.

5 The spreadsheet doesn't show what it's a counter to,
6 because the questions on the spreadsheet don't reflect what
7 was just argued here today.

8 MR. RAE: Your Honor, as I said before, I think
9 these -- these counters are -- I will acknowledge that the
10 spreadsheet is unclear. Kind of the spreadsheet format makes
11 it a little bit difficult to identify kind of fairness
12 counters that apply to larger blocks of testimony.

13 But the testimony that this relates to is the
14 testimony that's been designated from -- beginning on page 325
15 through I believe the end of page 328.

16 SPECIAL MASTER VANASKIE: Let me get there.

17 MR. RAE: The discussion of kind of the synthetic
18 chemical scheme that's discernible from the DMF carries over
19 for a number of pages in plaintiffs' questioning.

20 And I think if plaintiffs want to consider
21 withdrawing testimony to remove our counter, that's probably
22 something that we can kind of discuss and see if we can work
23 out what the breakdowns for that would be on our own.

24 SPECIAL MASTER VANASKIE: I just think -- I know this
25 is a simplistic response, but you're going to be playing

1 excerpts of the deposition. Both sides should have the
2 opportunity, in fairness, to designate parts of that testimony
3 that they think this jury should be able to hear.

4 And I think it's better if the jury hears it just
5 once in one method, in this case video testimony. I guess
6 Dr. Jaiswal will be here live, but you can then object as
7 duplicative if he testifies. And I assume he'll testify after
8 you present the plaintiffs' case. So you can avoid the
9 duplication.

10 But we'll allow it to come in here.

11 MR. NIGH: I think that's fair, as long as Torrent's
12 counsel understands the duplicative potential of Jaiswal
13 coming in and saying there's an open part of DMF and a closed
14 part of DMF and then we object, well, that's duplicative of
15 what you've already shown in the video.

16 SPECIAL MASTER VANASKIE: I just said that they
17 should be precluded from doing that. And obviously it's an
18 objection that you can make. And at the time of trial, you
19 can have the transcript from today's proceeding available to
20 you to say, the special master said that in the unique
21 circumstance of playing a video deposition and then having the
22 witness appear live and giving Torrent the full opportunity to
23 make designations from the video testimony, duplicative
24 testimony should not come in. All right?

25 MR. RAE: Your Honor, I understand your ruling. And

1 we will definitely take that under consideration.

2 I think that the scope of what's going to be
3 permissible to come in live is going to be decided by Judge
4 Bumb at trial ultimately, obviously.

5 And I think this issue that we're going back and
6 forth on kind of highlights why Torrent's position from the
7 outset has been that we offered to make Dr. Jaiswal available
8 to plaintiffs live during their case-in-chief, that we had a
9 preference for live testimony.

10 But Judge Bumb expressed a preference for live
11 testimony and for this to all happen in one go, and we're
12 being hamstrung here by plaintiffs' insistence on presenting
13 this witness who is going to be available live via video as
14 well.

15 But, again, I think those are trial management issues
16 for Judge Bumb and us to deal with at a later time.

17 SPECIAL MASTER VANASKIE: I think so as well. By the
18 way, I am also sensitive to the fact that the plaintiffs
19 should be able to present its case -- plaintiffs should be
20 able to present their case in the manner they believe is most
21 persuasive, and not having gone through this process of taking
22 depositions and deposition testimony can be presented to the
23 jury, they should be able to do so. So I'm trying to balance
24 those concerns.

25 One thing I know, the jury is going to get all the

1 information. I'm confident of that. All right?

2 Let's go to the next one.

3 MR. NIGH: Thank you, Your Honor.

4 MR. RAE: Thank you, Your Honor.

5 So our next objection is at page 333, line 24 to
6 334:4 and then continuing into the answer on line 7 to 10 of
7 page 334.

8 And I didn't --

9 SPECIAL MASTER VANASKIE: Hold on a second.

10 We're starting at page 334?

11 MR. RAE: 333, line 24, the question that begins at
12 the very bottom of that page.

13 SPECIAL MASTER VANASKIE: All right. The question
14 that starts, "Now, if you knew that those materials were being
15 used, then you could do a complete synthetic chemistry
16 analysis" --

17 MR. RAE: And I think Your Honor may have addressed a
18 similar issue already, but our objection here is that this is
19 an improper hypothetical that's not grounded in any facts,
20 that it's -- it's asking a fact witness, well, what if this
21 counter-factual was true. And that's opinion testimony, it's
22 not fact testimony.

23 SPECIAL MASTER VANASKIE: No. I will allow it. You
24 know, I think this is proper examination of a witness. I
25 don't think you need to tie this into any particular matter.

1 It's a question that says, can you do this? And he says yes,
2 if this complete scheme is available for the chemistry
3 scientist, it is possible. I think that's all right.

4 MR. RAE: Your Honor, I'm going to assume that that
5 ruling is going to apply to our next objection on 334:12 to 23
6 as well; is that correct?

7 SPECIAL MASTER VANASKIE: That's correct.

8 MR. NIGH: I think you have a counter here too, 335:1
9 to 16?

10 MR. RAE: Yes, we do. And I think this is the same
11 issue that we were just discussing about it's directly
12 responsive to the hypotheticals that we just addressed, which
13 is -- I think this questioning actually acknowledging that
14 their prior hypotheticals were based on information that
15 Torrent didn't have available to it, and Dr. Jaiswal agreeing
16 with that.

17 THE COURT: All right. I will allow it, the
18 counter-designation as well.

19 MR. NIGH: Okay.

20 SPECIAL MASTER VANASKIE: What do we have next?

21 MR. RAE: We have -- we're on to day 2 of Dr. Jaiswal
22 now. I'm sure everyone will breathe a sigh of relief that
23 we've at least gotten into the second day.

24 And then the next objection is at page 374. It's
25 the -- the question is from lines 12 to 18.

1 And our objection here -- actually, Your Honor, are
2 you there?

3 SPECIAL MASTER VANASKIE: I'm there now.

4 MR. RAE: Our objection here is that this is just a
5 question that really is attorney argument masquerading as a
6 question. They haven't even designated the answer to this
7 question. And then there's kind of a follow-on question that
8 begins on 375 and runs through to 376 that we haven't objected
9 to, but we think that this kind of testimony in the form of
10 a -- attorney commentary in the form of a question should not
11 be coming in.

12 MR. NIGH: Your Honor, just to clear it up, I think
13 it should also have 374, lines 21 and 22. That was missed.
14 That should be designated as well.

15 MR. RAE: And I think --

16 SPECIAL MASTER VANASKIE: I think this comes out.

17 The question here says, "'The focus of this guidance
18 is on DNA-reactive substances that have a potential to
19 directly cause DNA damage when present at low levels, leading
20 to mutations and therefore potentially causing cancer.'

21 "Do you see that?"

22 He answers: "Yeah, I read that."

23 I don't know what that does.

24 It just -- the question is, "did you see it?"

25 "Yeah."

1 MR. NIGH: It's going to the questions later, but to
2 the extent that, you know, that's your ruling, I understand.

3 SPECIAL MASTER VANASKIE: So that comes out.

4 What's the next one, Jacob?

5 MR. RAE: The next one is at page 400, line 12 to 19.
6 And then the answer which follows on line 22 of page 400 to
7 line 1 of page 401.

8 And this is an issue that's going to kind of carry
9 over to the next couple of objections, I think, but this is --
10 our objection here is that this is really attorney argument in
11 the form of a question. They're asking Dr. Jaiswal to comment
12 on ZHP's knowledge and actions.

13 And he's consistent in this answer and in other
14 answers that he can't comment about what ZHP did, whether or
15 not ZHP was right or wrong. Frankly, plaintiffs should be
16 asking ZHP witnesses those questions, not Torrent witnesses
17 those questions.

18 MR. NIGH: Your Honor, may I?

19 SPECIAL MASTER VANASKIE: Yes.

20 MR. NIGH: This is really surprising to me, because,
21 you know, frankly, that that's the argument. Torrent
22 exclusively -- and it's established all throughout this
23 deposition that Torrent exclusively relies on this statement
24 from ZHP when -- to state that the valsartan is free of
25 genotoxic risk. And they rely on that statement even when

1 they -- remember that discussion we were talking about where
2 the product was on hold and they put the product back on the
3 market? They're continuing to rely on the same statement.
4 When they know that they also have this same statement for
5 their new process drug from ZHP that was wrong, and that
6 product had NDMA and NDEA. So he gets to evaluate whether or
7 not the statement supplied by ZHP for their API supplier is
8 accurate or inaccurate.

9 I get to ask him those questions, because, frankly,
10 it was inaccurate. So they should have recognized that it was
11 inaccurate for the statement that was given to them for new
12 process, and, therefore, there's a real possibility it's
13 inaccurate for the old process as well.

14 MS. ROSE: Your Honor, may I be heard?

15 SPECIAL MASTER VANASKIE: Yes, certainly.

16 MS. ROSE: Hi. Thank you. Sorry. Nina Rose for
17 ZHP. I just wanted to weigh in on this issue because it
18 relates to my client.

19 I just want to clarify, because I don't have the
20 designations as they stand.

21 Is page 300 -- sorry, 399:9 through -- let's see, 19,
22 is that designated?

23 MR. RAE: 9 through 16 is designated on page 399
24 currently. And then lines 2 through 16 are designated on page
25 399, and then the rest of that page is not designated, and the

1 designation picks up again at page 400, line 12.

2 MS. ROSE: Okay. Thank you for clarifying that.

3 So ZHP's issue with this question is that they're
4 reading from a document that states that the vendor is
5 providing a declaration that in their drugs -- drug substance,
6 either genotoxic impurities are absent or controlled under the
7 unknown impurity at a control limit of .1 percent.

8 And then from there counsel is suggesting that this
9 was incorrect, that they were incorrect because there's NDMA
10 in the product.

11 But there's never been an allegation that the NDMA in
12 the product was above the 1 percent limit. So that is what
13 was represented, that they are absent or controlled under the
14 unknown impurity control limit of .1 percent.

15 So this is a very confusing and misleading question
16 by counsel, suggesting that they were wrong because NDMA and
17 NDEA were in the product, because they were not above
18 the .1 percent control limit.

19 That's our issue. It misleadingly suggests this to a
20 Torrent witness who would have no -- as he says, can't comment
21 on the ZHP documents. That statement is just hanging out
22 there. That's a misrepresentation of what ZHP said and
23 suggesting that it was false when it wasn't.

24 SPECIAL MASTER VANASKIE: All right. Daniel?

25 MR. NIGH: Your Honor, there's two issues here. One,

1 we're going to see a further genotoxic declaration that does
2 not include the .1 percent. But on top of that, that
3 genotoxic declaration is obviously tracking the language from
4 the guidelines. In the 2000 -- those guidelines that we
5 talked about in the 2006 EMA document, it's tracking that
6 language. And that's the purpose of the -- of the
7 declaration. And if we look at that language, the way in
8 which it's tracking that language, it's not .1 percent. It's
9 "genotoxic risk or .1 percent for another unknown impurity."
10 Very clear.

11 And so we think that that language obviously tracks
12 the language that's coming from the EMA guidelines and
13 ultimately implemented into the ICH Q3A, and, therefore, it is
14 a misrepresentation.

15 MS. ROSE: Your Honor, may I respond to that very
16 quickly?

17 SPECIAL MASTER VANASKIE: You may.

18 MS. ROSE: I appreciate it. Thank you.

19 So I think what Mr. Nigh is saying here is that you
20 shouldn't look at the question that was asked, you should look
21 at an EMA document that this tracks.

22 But the question relates to that there was a
23 warranty, and it quotes what the warranty allegedly was, which
24 says "either genotoxic impurities are absent or controlled
25 under an unknown impurity limit."

1 That's what this testimony is. If Mr. Nigh is
2 referring to other testimony that doesn't include that
3 language, then that's a different question and we can look at
4 that. But for this particular question and this particular
5 warranty, it is misleading to suggest that this was not true.
6 Because there's expert testimony that the impurities were
7 below .1 percent, and I don't believe plaintiffs have any
8 evidence that the impurities were above .1 percent.

9 So just looking at this testimony, this is
10 misleading.

11 SPECIAL MASTER VANASKIE: All right. I am persuaded
12 to exclude this testimony. Sustain the objection to it.

13 Let's make clear what's being excluded. Page 399
14 from lines 9 through 19 and then from lines 23 on page 399
15 through all of page 400 to page 401, line 1; is that correct?

16 MR. NIGH: Your Honor, I do think there are two
17 separate issues here.

18 And one is a strict reading as argued by Nina Rose of
19 "The vendor provided declaration on October 9, 2009, that in
20 their drug substance, either genotoxic impurities are absent
21 or controlled under unknown impurity at a control limit
22 of .1 percent."

23 So that exclusion may make sense all the way to page
24 400, line 10.

25 But there's another statement as well. "They further

1 declared that there is no genotoxic risk." That's page 400,
2 line 12.

3 And then the questions go from there to discuss, is
4 there a genotoxic risk? That's a different statement than the
5 one proposed further above.

6 SPECIAL MASTER VANASKIE: I agree with you.

7 MS. ROSE: Your Honor, could I be heard on that?

8 SPECIAL MASTER VANASKIE: Sure.

9 MS. ROSE: But the beginning of that question on
10 page -- I believe it's 400, line 12, it's saying they were
11 wrong with that statement. There it's still referring to the
12 statement that is referenced on page 399. And that's not what
13 the statement says. It doesn't say that they warranted that
14 it was not genotoxic. They said it was -- "that genotoxic
15 impurities are absent or controlled under unknown impurity at
16 a control limit of .1 percent."

17 It's simply not true that they said that they were
18 not -- that there was no genotoxic risk. That's not anywhere
19 in that statement. That again is a misleading statement by
20 plaintiffs to a Torrent witness about a ZHP document and an
21 alleged ZHP warranty.

22 The witness wouldn't have the ability to answer that
23 question or dispute it, so it's unfair to be asking these
24 questions misrepresenting a ZHP document to a witness.

25 MR. NIGH: Your Honor, the word "further" makes it

1 clear that this is not the language above that's quoted, "the
2 vendor provided declaration." The word "further" makes it
3 clear that they further declared there is no genotoxic risk.
4 That's different than declaring that it's under a certain
5 percentage.

6 MS. ROSE: Your Honor, in all respect to Mr. Nigh,
7 there's no representation -- there's no reference to a
8 different representation. This is all one line of
9 questioning. Their declaration is that it wouldn't be in
10 their drug substance. That was wrong. That's on page 400,
11 line 2. And the witness says, "I'm not able to say that."

12 And then Mr. Nigh says, "They further declared there
13 is no genotoxic risk.

14 "Let's look at that.

15 "They were wrong with that statement, correct?"

16 He's talking about the same document and the same
17 statement. This isn't like a new document that he's
18 introduced where he said that there was no genotoxic risk.
19 That's just not -- that's not what was stated in the document.
20 This is counsel representing the document that was discussed
21 on page 399.

22 MR. NIGH: Your Honor, that is just wholly
23 inaccurate. The document says "there is no genotoxic risk" in
24 the document. I don't know what we're arguing here. I
25 recognize that the first one has quotes around it, but the

1 document further states there is no genotoxic risk, that's in
2 the document.

3 SPECIAL MASTER VANASKIE: I don't have the document
4 in front of me, so that's part of the problem.

5 If the document has that statement that there's no
6 genotoxic risk, then the questions on page 400 from line 12 --
7 that question from page 400, line 12 through line 19 would be
8 not objectionable and should be answered, and the answers
9 would go to page 401, line 13, I take it.

10 So I think that it can come in, as long as the
11 document, this declaration, says there's no genotoxic risk.

12 MR. RAE: And just to clarify for the record, the
13 page 401, line 3 to 13 has not been designated by plaintiffs.

14 So any ruling here I think would end at page 401,
15 line 1, which is the end of plaintiffs' designation, to my
16 understanding.

17 SPECIAL MASTER VANASKIE: Thank you for that. That's
18 true.

19 All right. Anything else on this?

20 (No response.)

21 SPECIAL MASTER VANASKIE: What's our next objection?

22 MR. RAE: The next objection is on page 412, line --
23 the question at the bottom, line 22, that carries over with
24 the answer to page 413, line 9.

25 And the objection from the Torrent perspective is the

1 same objection as the one that we were just discussing.

2 MR. NIGH: I'm sorry, Jacob, are you on page 411,
3 line 18 to page 412:24?

4 MR. RAE: Yes. But as is noted in our objections,
5 the objection only applies to the question that begins at
6 412:22 and the answer to that question on the next page.

7 MR. NIGH: Judge, I think we should just include it,
8 because now it's becoming even more clear that we should
9 include just -- I mean, it's included, it's designated, but if
10 you look right up there, it's quoted that their API is free
11 from genotoxic impurity.

12 And then I even ask, "Let's underline 'free from
13 genotoxic impurity.'"

14 So this is different. This is not a .1 percent.
15 None of that is in here.

16 SPECIAL MASTER VANASKIE: Well, I have the same
17 ruling, this should come in. To the extent there's an
18 objection, it's overruled.

19 MR. RAE: Thank you, Your Honor.

20 My previewing that I thought it was the same issue
21 was intended to hopefully shortcut rehashing the same
22 arguments again.

23 SPECIAL MASTER VANASKIE: Yes.

24 MR. RAE: Our next objection is at 425, lines 17 to
25 19. And I'll pause for a second to make sure everyone is

1 there.

2 MR. NIGH: Was the one at 413:5 through 9 withdrawn?

3 MR. RAE: That's the same, it's the objection to the
4 question and the answer. It falls under the ruling we just
5 discussed.

6 MR. NIGH: Okay.

7 SPECIAL MASTER VANASKIE: So where are we at now,
8 Jacob?

9 MR. RAE: 425, lines 17 to 19.

10 SPECIAL MASTER VANASKIE: What's the basis for the
11 objection?

12 MR. RAE: This is -- Mr. Nigh asked a question here,
13 and Ms. Brancato objected to that question on then -- on a
14 form basis, and Mr. Nigh asked a reframed version of the same
15 question that we're not objecting to.

16 Mr. Nigh's decision to reframe and reask his question
17 implicitly acknowledges that the objection was being accepted
18 at that point in time, and he shouldn't be able to designate
19 the objected question that was never answered.

20 SPECIAL MASTER VANASKIE: So you're seeking to strike
21 what's at page 425 from line 17 through line 22?

22 MR. RAE: No, Your Honor. Just 17 to 19. We're --
23 yes, through -- they didn't designate 20 to 22, but yes.

24 SPECIAL MASTER VANASKIE: So we pick up at 425, line
25 23?

1 MR. RAE: Yes.

2 MR. NIGH: And, Your Honor, without seeing the
3 testimony that's designated above, that kind of makes sense,
4 but we actually went through and calculated 4.7. Easy to
5 calculate. He did it. He agreed. That's what the ICH M7
6 guidelines are showing.

7 And just to be clear, ZHP is making a genotoxic
8 statement now that says it's manufactured in accordance with
9 the ICH M7 guideline, with the guideline. And so that we go
10 through, we do the math, and we show that would be 4.7 ppm.
11 He agrees.

12 And so this isn't just -- this is comparing the
13 calculation to what we see here. It's not compound. It's
14 compare the calculation to what we see here.

15 And the objection comes in the middle of the
16 question.

17 SPECIAL MASTER VANASKIE: Well, the point is the
18 question that starts on line 17 is never answered.

19 MR. NIGH: It's just a comparison, what we calculated
20 to what we're seeing here. And he says, "Yeah, I seen that."

21 SPECIAL MASTER VANASKIE: You can pick that up at
22 line 23.

23 MR. NIGH: But the line 23 doesn't actually refer
24 back to the calculation saying it's the same as what we see
25 here.

1 SPECIAL MASTER VANASKIE: What's the -- where's the
2 answer?

3 MR. NIGH: 426:1.

4 SPECIAL MASTER VANASKIE: The question that starts on
5 line 17.

6 MR. NIGH: It's answered at 426:1 and then reiterated
7 at 426:4.

8 SPECIAL MASTER VANASKIE: "Yeah, I seen that." He's
9 answering the earlier question.

10 MR. RAE: Your Honor, I think -- the way depositions
11 work is, as everyone here knows, sometimes a question gets
12 asked, there's an objection, and the question gets reframed.
13 And when that happens, the witness doesn't answer the prior
14 question that was reframed, the witness answers the new
15 question that follows the objection.

16 That's what's happening here. They asked a question,
17 there was an objection, then they asked a different question.
18 That's exactly what they show here.

19 The witness says, "Yeah, I seen that." That's a
20 response to the question on 425, line 23 to 24, not a response
21 to the different question that was objected to and --

22 SPECIAL MASTER VANASKIE: I agree. I agree. So
23 we're going to strike from -- on page 425, lines 17 to 22.
24 All right?

25 MR. RAE: Thank you, Your Honor.

1 SPECIAL MASTER VANASKIE: What's next?

2 MR. RAE: Next is page 428, lines 14 to 20. And then
3 the answer from line 23 to 429:1.

4 And I think this goes back to the prior discussion
5 about asking Torrent witnesses to comment on what ZHP knew, so
6 I think your prior rulings address our objection here, unless
7 someone has a different view.

8 MR. NIGH: Yeah. I think it's the same sort of prior
9 ruling that they're making representations about genotoxic
10 impurities, and we agree that that information comes in.

11 SPECIAL MASTER VANASKIE: ZHP has a different view.

12 MS. ROSE: No, no. I wanted to make sure I was on
13 the right page so I can just take a look at the testimony.

14 SPECIAL MASTER VANASKIE: Okay.

15 MS. ROSE: Are we on 429?

16 MR. RAE: It's the last question that begins at
17 428:14 and then stretches to the top of 429, just 429:1.

18 And if it's helpful, there's no other questions or
19 answers designated on those pages. It's just this one
20 question and answer.

21 MS. ROSE: Okay. Thank you.

22 SPECIAL MASTER VANASKIE: And I will allow it.

23 Are we up to page 435 now?

24 MR. NIGH: Your Honor, I think just in light of kind
25 of some of the rulings before, we would ask that 428:9 to 13

1 also be included, because I think that's making this more
2 clear now, since we removed it once before.

3 SPECIAL MASTER VANASKIE: So you want to include 429,
4 lines 3 --

5 MR. NIGH: No, I'm sorry. I meant we want to include
6 428:9 to 13.

7 SPECIAL MASTER VANASKIE: That's fine.

8 Where are we going to now?

9 MR. RAE: Our next objection is 439:5 to 440:8.

10 And, Your Honor, the objection here is -- I think
11 it's most helpful if you go up to page 438. This is
12 questioning about an inspection investigation report by the
13 FDA that was conducted of ZHP's facility.

14 I think the most helpful question here is at 438:5 to
15 9.

16 Question: "Now, before today, have you ever seen
17 this EIR, this inspection report of ZHP's facility that was
18 done in 2017?"

19 Answer: "No, I have not seen it."

20 And then plaintiffs go on to ask Dr. Jaiswal about
21 this ZHP document, about an inspection of a ZHP facility by
22 the FDA. Inspection investigation reports are not available
23 publicly. And that he has testified that he's never seen
24 before. And they ask him a number of questions about those
25 documents.

1 And our objection is that there's no foundation for
2 asking Dr. Jaiswal about an inspection of a ZHP facility
3 conducted by the FDA and the report about it that he never saw
4 and that Torrent never received.

5 MR. NIGH: Your Honor, may I respond?

6 SPECIAL MASTER VANASKIE: You may respond.

7 MR. NIGH: There's numerous ways that this is
8 relevant, but in terms of getting into the information that's
9 found in the EIR report, we're able to -- because these are
10 the activities with what's going on at ZHP and specifically
11 relevant to what's going on with ZHP related to the valsartan
12 product that the -- the API that they've manufactured and sent
13 to Torrent for years. And so we can ask them if they ever
14 were aware of information similar to this or did they even
15 know about this information.

16 And the reason it's -- this is a 2017 inspection
17 report. It's not like this came out of nowhere. So to say
18 that it's not available publicly, well, yes, it is. Yes, it
19 is. There are many places that you can just look up FDA
20 inspection reports online, and you can just get them online,
21 let alone -- in other words, you can just order them and you
22 can get inspection reports. Yes, there may be some
23 redactions, but you can get them.

24 Second, they can obviously get them via an audit or
25 even just asking their API supplier, hey, if you ever get an

1 FDA report, you can send that to us. I mean, please send that
2 to us immediately about -- regarding any inspections.

3 So our experts have said that that's available to
4 them. There's no evidence that says it's not, that they can't
5 do that.

6 So there's many different ways that they could have
7 found out the information that's in this report. And we want
8 to look at it and see, okay, this is the information that the
9 FDA is citing that they found, were you ever aware of these
10 issues? Because Torrent has their own independent duty to
11 audit. They don't just get to rely on the FDA. They have
12 their own independent duty, many other ways to audit. And so
13 we get to then be able to explore, were you aware of these
14 issues that the FDA found were problems, and specifically
15 relating to the valsartan API.

16 MR. RAE: Your Honor, if I may, we're not objecting
17 to the question that establishes that Dr. Jaiswal never had
18 seen this document before, which is the question that goes to
19 this line of questioning that Mr. Nigh is now positing that
20 wasn't the line of questioning that was conducted at the
21 deposition about they're allowed to ask if Torrent received
22 this report. They might even be allowed to -- they didn't, so
23 we're not talking about this right now. I don't want to get
24 ahead of myself and kind of say that they would be allowed to
25 ask.

1 But it would be a very different question if they had
2 been asked a series of questions about whether or not Torrent
3 was aware of information -- factual information that the FDA
4 may have discovered in this inspection. But the questions
5 that they actually asked are -- they just read from the EIR
6 and say, do you see that?

7 So 439:5 to 16 is a series of quotes from the EIR
8 followed with the question, "Do you see that?"

9 The next question, line 19 to 6 on 439, line 19 to
10 446 is again is a long quote read by counsel with a question,
11 "Do you see that?"

12 Those are not fair questions to ask. There's no
13 foundation for those questions. The witness hasn't seen this
14 document before. Using him to read into the record the
15 contents of the document, which whether or not it can come in
16 as evidence, our objection isn't even a relevance objection
17 here. It's simply a foundation objection. This is the wrong
18 witness and the wrong questions.

19 MR. NIGH: Your Honor, as the 30(b) (6) on oversight
20 of API suppliers, this is precisely the witness for this
21 information.

22 But I will say, in reading -- to get to the bottom,
23 we had designated 442:14 to 20. And along with that, sort of
24 inside on the objection to form that we looked at earlier and
25 the rephrasing of the question, I think that actually our

1 designation -- recognizing that ruling should exclude 442:14
2 to 20 and, rather, include 442:24 to 5, which is the ultimate
3 end result.

4 We read off all these specific violations, were you
5 aware of any -- was that information ever conveyed to you.
6 Again, these happened in 2017. So this is while they're still
7 selling the drug before the recall, so this is extremely
8 relevant.

9 "Were you ever aware of these issues?" And keeping
10 in mind, Torrent has an independent duty to audit. And he
11 finishes -- the ultimate exclamation point on all this
12 information that makes it relevant through Jaiswal is the
13 answer on 443, 4 and 5, "I'm not really aware of this
14 information."

15 The fact that he has no idea is what makes it
16 relevant.

17 SPECIAL MASTER VANASKIE: So were you suggesting,
18 Daniel, then that you be allowed to -- ask what question?

19 MR. NIGH: All the questions preceding that go to the
20 insight of that specifically what was found. We would
21 withdraw 442, question 14, since there was an objection to
22 form on that one.

23 SPECIAL MASTER VANASKIE: Okay.

24 MR. NIGH: But then we have line 442:24 through to
25 443:5, where the witness ties it together and says, "I'm not

1 really aware of this information."

2 SPECIAL MASTER VANASKIE: Jacob?

3 MR. RAE: I think if we skipped all of the reading
4 out from the document and just asked, has he seen this
5 inspection report before, no, I have not seen it, and then cut
6 to the question that Mr. Nigh just highlighted of was this
7 information ever communicated to you and he says no, that's
8 all appropriate questioning.

9 But the intervening reading from the document and
10 asking the witness, did you see that, this is just -- this is
11 plaintiffs presenting their case against -- frankly, they're
12 presenting their case against ZHP through a Torrent witness
13 who is incapable of addressing these issues because he doesn't
14 know anything about this document. He's never seen it before.

15 And I'm confident that plaintiffs are going to
16 present this document through ZHP witnesses. They're going to
17 ask about the contents of these documents. Those witnesses
18 will provide the answers that ZHP has to offer explanations or
19 context where it's appropriate to the contents of this
20 inspection report.

21 And doing it through a Torrent witness is improper.
22 Establishing that Torrent didn't know this about this document
23 and its contents, we have no objection to that.

24 MR. NIGH: Your Honor, if I may, just to go a little
25 bit further. This is not about ZHP. This is precisely about

1 Torrent and Torrent's independent duty to be aware of this
2 information, their independent duty to oversee their API
3 supplier.

4 This information came out in 2017, and they never --
5 and in his answer, "I'm not really aware of this information,"
6 is the exclamation point. That's what makes it relevant.

7 SPECIAL MASTER VANASKIE: What I have a problem with,
8 Daniel, is you reading from the report.

9 MR. NIGH: The -- sorry.

10 SPECIAL MASTER VANASKIE: And saying, did you see
11 this?

12 MR. NIGH: To be clear, my question is not did you
13 see this and did this. My question is, were you aware of this
14 information. It goes a little bit further than just saying,
15 have you ever seen this report.

16 Because a lot of times in business, that's not how
17 information gets communicated. It may not be that they saw
18 the precise report, but it may have gotten back to Jaiswal one
19 of a number -- a hundred different ways than just actually
20 seeing the report.

21 So I read to him the specific statement found by the
22 FDA and were you aware of this information. It's not based on
23 did you just get it from the report, did you get it from
24 anywhere. Did ZHP ever call you up and say, hey, we've got
25 this problem? Did Jenny Yang ever go to the inspection

1 facility and find out, oh, there's this information, or
2 anybody conveying that information in any way up its way all
3 the way to Jaiswal? And it's not even just to Jaiswal,
4 Torrent in its capacity as a 30(b) (6) witness.

5 So I'm not really aware of this information. And was
6 this information ever conveyed to you is much, much more
7 broader than just the were -- did you ever see this document.
8 That's why you have to read the -- the specific allegation and
9 then say, were you ever aware of this information or was it
10 ever --

11 MR. RAE: Your Honor, if I may, as I said before, I
12 think the testimony that Mr. Nigh is referencing now that he
13 didn't previously designate of "was that information ever
14 conveyed to you" and Dr. Jaiswal saying that he's "not really
15 aware of this information," I'm not objecting to his desire to
16 add that to the testimony.

17 The problem is that everything that comes before that
18 is Mr. Nigh reading from a document and asking, do you see
19 that, for a document that there's no foundation for.

20 And I think Mr. Nigh has articulated a line of
21 questioning that may or may not have been something that he
22 could have reasonably pursued with this witness during his
23 deposition, but it's not the line of questioning that he
24 actually pursued in this deposition.

25 He doesn't get to designate testimony simply because

1 if he had asked a different set of questions that got at the
2 same issue, those questions might have been appropriate.

3 Here, he reads from a document the witness has never
4 seen before and says, "Do you see that?" He doesn't get to
5 use Dr. Jaiswal as a backboard to read from a document that's
6 not a Torrent document that Dr. Jaiswal and Torrent don't
7 have.

8 MR. NIGH: Your Honor, if I may, if I were to try to
9 do this in some conclusory way, then the defendants would be
10 objecting and saying that mischaracterizes the evidence. So
11 it's not done in a conclusory way. It's done precisely with
12 the statement that FDA made and then asking, were you ever --
13 was this information ever conveyed to you. That's the most
14 direct way that information can be asked.

15 And he is the leader of quality and safety,
16 overseeing API supply and designated specifically on these
17 topics for 30(b)(6).

18 SPECIAL MASTER VANASKIE: I will allow the testimony.

19 It's clear to me this information should be presented
20 to the jury. It's clear to me that it should come in in some
21 manner. This is a little unusual way to present the
22 information in my experience, but I don't think it's improper.

23 MR. RAE: Your Honor, if I may, because we've been
24 mostly focused on our 602 objection, but we also have a 403
25 objection here. And I think Your Honor is absolutely correct

1 that this is an unusual way to get this document in.

2 I don't think Mr. Nigh can sit here and tell you that
3 the contents of this document aren't going to come in through
4 the case against ZHP and the examination of ZHP's witnesses.
5 So I don't think there's a concern here about the document or
6 questions about this document excluded.

7 But it's unfairly prejudicial to Torrent to have this
8 document get read to a Torrent witness, because it's going to
9 imply to the jury and it's going to confuse the jury about --
10 they're going to hear these long questions about things that
11 the FDA found about ZHP, do you see that, yes, it's here. And
12 what the jury is going to take away from that is that this is
13 stuff that Torrent knew. And Torrent didn't know that.

14 SPECIAL MASTER VANASKIE: Excuse me for interrupting
15 you, but the answer to the question is, I'm not aware of this.
16 That's what he says repeatedly.

17 Yeah, I am not aware of this, what we are seeing
18 here.

19 MR. RAE: Your Honor, that's absolutely right, but
20 that doesn't cure the prejudice of the kind of prolonged
21 questioning about the document that he hasn't seen before.

22 There needs to be a foundation to ask the witness
23 about a document. There's no foundation for these questions
24 with Dr. Jaiswal, and they're prejudicial because of that lack
25 of foundation.

1 MR. NIGH: Your Honor, the foundation is laid in the
2 prior testimony.

3 SPECIAL MASTER VANASKIE: Yeah, I think the
4 foundation is laid.

5 We need to move on here. I would allow this
6 examination.

7 MR. NIGH: Jacob, where do you believe this goes
8 through to?

9 MR. RAE: I think this goes through your designation
10 at 445:24, would be the end of -- beginning 439:5 to 445:24.
11 To the extent we have objections to testimony in there, I
12 think Judge Vanaskie has just addressed all of those.

13 MR. NIGH: Okay. So I think our next one is page
14 463:14; is that right?

15 MR. RAE: Yeah. And just to clarify for our sake,
16 and for the record, and we can work this out afterwards too,
17 but I think you withdrew one question within that set at
18 442:14 to 20 and replaced it with the question at 442:24 to
19 443:5, leaving aside the interposed objection that will
20 obviously come out. Is that right?

21 MR. NIGH: Because I had gone further down.

22 Yes. Withdrawing 442, lines 14 to 20, because that
23 had an objection to form, then was reworded and including
24 442:24 to 443:5.

25 MR. RAE: Okay. Great. I just wanted to make sure

1 that we had that clear for the record.

2 SPECIAL MASTER VANASKIE: Very well. Good.

3 MR. RAE: So I think the next one is -- it's really
4 your objection to our counter from 464:20 to 465:14.

5 MR. NIGH: Okay. So I guess to the extent you've got
6 106, 464:11 to 164:19, you would simply be arguing that in
7 order to be complete, it needs to have 464:20 to 465:14?

8 MR. RAE: Correct. And this is a straightforward
9 completeness. The question "Okay" is interjecting and cutting
10 off the answer, and then the next one, "I understand that.
11 Sorry. Go ahead," is the same. We simply want to have the
12 full answer from Dr. Jaiswal come in to this question.

13 MR. NIGH: Yeah. I don't have any -- I've understood
14 the prior rulings, and I think that that comes in now.

15 SPECIAL MASTER VANASKIE: Yeah, I think it's fine.

16 What's next?

17 MR. RAE: I think I may have had an objection at
18 469:19, but I'm withdrawing that.

19 SPECIAL MASTER VANASKIE: All right.

20 MR. RAE: So the next is 470:24 to 471:2. And then
21 the kind of sequence of questioning and answering kind of
22 proceeds over the course of the next page. I think these are
23 all going to be the same issue.

24 MR. NIGH: Your Honor, essentially what's happening
25 in this question -- and there's a decent amount of questioning

1 here that's going to be related, I think, almost all the way
2 probably to 474:10, each of those questions.

3 ZHP provided chromatograms to Torrent as part of the
4 validation process before they even started selling valsartan
5 into the market. And those chromatograms essentially will
6 show the various impurities that you're going to see in the
7 drug. And one of those is specifically on residual solvent.
8 So we looked at the residual solvent chromatograms, we point
9 them out. And what we see is we see, okay, there's a few of
10 the peaks that are labeled and then there are peaks that are
11 not labeled.

12 And this is troubling, obviously, to the plaintiffs'
13 case, because not knowing what those unknown peaks are is
14 problematic. And this is precisely how Novartis discovered
15 there was NDMA in the product. Novartis was also a finished
16 dose manufacturer who received chromatograms. And when they
17 had unknown peaks, they went a step further. They sent it to
18 a lab to figure out and label what those peaks were. And
19 that's how they ended up finding out that an unknown peak was
20 NDMA. And precisely the location of where these unknown peaks
21 is precisely the problem, because the location of the unknown
22 peak is right where you would expect NDMA and NDEA to dilute.

23 And so that's why this is all being pointed out,
24 here's this unknown peak, it's right, it's here, here, here,
25 and showing it time and time again.

1 And it builds up to that -- what I just said in terms
2 of that commentary on, hey, this is how Novartis found the
3 problem. Torrent could have done the same thing.

4 MR. RAE: Your Honor, if I may, I think what Mr. Nigh
5 said highlights the problem here. Plaintiffs want to use this
6 line of questioning about not unknown but unlabeled peaks on
7 chromatograms. And the peaks that they're asking about are
8 extremely large peaks. They're the peaks that respond to
9 diluent, to the material that's being used to -- like to help
10 identify the solvent. It's basically the control for the
11 chromatogram. And they're pointing to that material and
12 saying this doesn't have a label. Dr. Jaiswal, you sitting
13 here today, from this ZHP document about their chromatography
14 results, can't tell me exactly what this peak corresponds to.

15 But we all know plaintiffs' expert, Dr. Hecht, in
16 this case testified that you wouldn't be able to identify NDMA
17 or NDEA peaks on these chromatograms because they would be so
18 tiny you wouldn't notice them unless you knew to look for
19 them.

20 The peaks that they're asking about here are gigantic
21 peaks. And the questioning is designed to mislead the jury
22 into thinking that these peaks have something to do with NDMA
23 or NDEA, when, as a factual matter, every lawyer in this case
24 and the experts in this case know that they do not.

25 MR. NIGH: Your Honor, may I respond?

1 SPECIAL MASTER VANASKIE: Yeah.

2 MR. NIGH: It's precisely incorrect.

3 The size of these peaks is not the large peak that
4 would be typically diluent.

5 This witness, if he wants to, he can respond to that.

6 He does. But we can point out and see if he has an answer for
7 that, and he does. On some of them he says he thinks it's
8 diluent.

9 I think it's kind of funny that the defendants are
10 trying to change the terminology from "unknown peak" to
11 "unlabeled peak." Because "unknown peak" is the terminology
12 all throughout the FDA's documents, it's all throughout
13 Torrent's documents, it's all throughout ZHP's documents.

14 I mean, this is the first time we're hearing
15 "unlabeled peak." And I think there's a reason, because they
16 don't like the terminology "unknown peak." So now we're
17 seeing this sort of interjection of some odd labeling.

18 But to make my point clear, they refer to some
19 statements from Dr. Hecht that are taken out of context. What
20 they don't do is they don't refer you to the statements made
21 by Dr. Najafi, who is the analytical chemist who does
22 precisely this, and states that had they looked at these
23 unknown peaks, they could have labeled these peaks and they
24 would have been able to do precisely what Novartis did.

25 MR. RAE: Your Honor, I think the fundamental issue

1 here is that none of their experts are going to get up on the
2 stand and say that these peaks that they are asking about here
3 are NDMA or NDEA because they're not. And if they were, this
4 would very well be a different conversation that we would be
5 having. I think it would be a very different, like, potential
6 objection or maybe no objection at all. But they're not.

7 And asking these questions in the context of this
8 case where the jury is going to hear all about unknown peaks,
9 all about what Novartis did, all about how this impurity was
10 discovered and the presence of it was discovered, and they're
11 going to pursue this misleading line of questioning that
12 implies that Torrent had access to information that would have
13 revealed that by reference to documents that have nothing to
14 do and questions that have nothing to do with peaks that would
15 have corresponded to NDEA and NDEA.

16 MR. NIGH: Judge, I think there's selective hearing
17 here because I think that the defendants like to take the
18 information -- the answer, the sound bite they got from
19 Dr. Hecht and just completely close their ears off to
20 everything Najafi said.

21 This is discussed extensively in his report,
22 extensively. So to say nobody is going to get on the stand,
23 of course they are.

24 SPECIAL MASTER VANASKIE: Listen, fellows, I'm trying
25 to figure out what testimony gets presented to this jury by

1 way of these video depositions. You're not helping me out,
2 respectfully, in getting to that bottom line.

3 I know you've got arguments that you're going to
4 make. I just want to find out what's not admissible about
5 this testimony or why is it inadmissible. Is it because they
6 can suggest something that's not true? And why isn't your
7 ability to counter that sufficient to say, it still comes in
8 and you can point out that those large peaks are not NDMA or
9 NDEA?

10 You can say what they are, but the jury gets to
11 evaluate the evidence. That's what it seems to me should
12 happen.

13 MR. RAE: Your Honor, I think our position here is
14 that it would be unfairly prejudicial, confusing and
15 misleading to the jury and that Rule 403 should bar this
16 evidence, but I think I understand Your Honor to be saying you
17 disagree with that position. So if that's the case, I am not
18 going to belabor the point on this one, but that's the basis
19 for our objection here.

20 SPECIAL MASTER VANASKIE: Yeah, that is the point.
21 And you have the ability to explain to the jury, no, that
22 these peaks are not NDEA or NDMA, and that's that.

23 But plaintiffs should be able to present their case
24 as they -- as they intend to. So I am not sure where that
25 leaves us in terms of do I have page and line numbers that I

1 can make clear come in?

2 MR. NIGH: I think that that's relevant to everything
3 from page 470, line 24, all the way through to page 474, line
4 10.

5 MR. RAE: I would agree with that. We can treat all
6 of those as a group.

7 SPECIAL MASTER VANASKIE: All right. So what are we
8 up to now, page 475, line 23?

9 MR. RAE: I think our next --

10 MR. NIGH: Sorry. Go ahead, Jacob.

11 MR. RAE: I think our next objection is page 555,
12 line 7 to page 556, line 1.

13 MR. NIGH: We skipped forward almost a hundred pages
14 there.

15 MR. RAE: Yes, we did.

16 SPECIAL MASTER VANASKIE: Page 555, line 7?

17 MR. RAE: Sorry. Actually, the objection is only
18 to -- I misread that -- 555, line 18 to 556, line 1.

19 And, Your Honor, this is a similar issue to the other
20 objection that you sustained earlier, which is that there's a
21 question here. There is an objection. There's then some
22 cross-chatter amongst the attorneys. There's then another
23 kind of statement by Mr. Nigh that's directing what's going to
24 happen. And then at 557, line 8, there's a new question
25 that's being asked.

1 And again, we're not -- there's a line of questioning
2 there that we have no objection to. So we simply want this
3 unanswered question to be out.

4 SPECIAL MASTER VANASKIE: Yes. I think from page
5 555, line 18 through page 557, line 6 is out.

6 MR. NIGH: That's right. I agree, Your Honor.
7 We would withdraw -- we only made the designation of -- we
8 would withdraw 555, line 18 to 555:6, one, because I go on to
9 rephrase the question later anyways.

10 SPECIAL MASTER VANASKIE: But I think we strike the
11 colloquy that occurs on page 556 between you and Ms. Brancato.

12 MR. NIGH: That's right. We didn't designate any of
13 that. So the next designation is 557:8, yes.

14 SPECIAL MASTER VANASKIE: So what's our next page
15 number for objections?

16 MR. RAE: Our next objection is page 560, line 11 to
17 18.

18 SPECIAL MASTER VANASKIE: That question is, "So that
19 email is dating all the way back to May 24, 2018, where they
20 are talking about proceeding the investigation on unidentified
21 peaks, right?"

22 And you have an objection to that?

23 MR. RAE: Correct, Your Honor. And our objection
24 here is similar to the other objection that you overruled
25 earlier, which is this question, and there's going to be

1 several questions that follow this that are going to be a
2 similar issue.

3 But plaintiffs are asking Dr. Jaiswal about
4 correspondence between Novartis and ZHP. This is not Torrent
5 correspondence. It's not correspondence that Dr. Jaiswal had
6 seen before. It's not correspondence that Torrent possessed.

7 And we've tried to be limited in our objections, so
8 we've let in some of the foundational kind of questions about
9 what this document is without objecting to them.

10 But when they start asking questions that start to
11 kind of call for Dr. Jaiswal to comment on the content of this
12 document, we think it's inappropriate, there's no foundation
13 to ask him about this, and that it's prejudicial to Torrent,
14 again, to allow plaintiffs to ask questions about ZHP's
15 correspondence with Novartis of a Torrent witness.

16 And to be clear, again, as we've discussed before,
17 this is not an issue of whether or not this document or this
18 correspondence is going to come before the jury. This is a
19 part of plaintiffs' case. They're going to present it through
20 ZHP witnesses who would know something about this. And the
21 objection here is that it's prejudicial to let them present
22 ZHP's correspondence with Novartis through a Torrent witness.

23 MR. NIGH: And, Your Honor, the questions are
24 actually related. As we get down to the end, we will see,
25 were you aware of any information similar to this. He has to

1 be able to see what the information is to see if he's ever
2 been aware of any information that's been given to him or
3 conveyed to him that's similar to any of this information. So
4 his lack of knowledge, just like his lack of knowledge with
5 the 2017 EIR, is the problem.

6 SPECIAL MASTER VANASKIE: Yeah, I will allow this.

7 MR. NIGH: And where does this end, do you recall,
8 Jacob?

9 MR. RAE: I think this would apply to our same
10 objections and I assume the same ruling are going to apply to
11 the testimony designated from 561:9 through 565:12.

12 MR. NIGH: I think that's correct.

13 SPECIAL MASTER VANASKIE: Yeah. And you'd get the
14 same ruling from me.

15 MR. NIGH: Okay.

16 MR. RAE: I think we have similar objections and I'm
17 guessing we're going to get a similar result to the testimony
18 that we've objected to on page 575, which is -- this is a
19 little bit different. This is asking about the report that
20 Novartis commissioned from Solvias with respect to its
21 investigation.

22 So kind of we're even a step further removed from
23 Torrent here, because they're asking about Torrent --
24 Novartis's communications and the report Novartis received
25 from its consultant Solvias about the investigation that

1 Novartis did.

2 Again, the first question here is asking what
3 Novartis did, the witness testifying that he's not aware of
4 it.

5 The next question is about what Novartis did. The
6 witness is testifying that he doesn't know about it.

7 It's -- there's -- it's prejudicial to permit them to
8 ask these questions about something that there's no reason
9 this witness would know about.

10 MR. NIGH: Your Honor, if I may, this was discovered
11 in May of 2018. I think the issue that they're not aware of
12 this is precisely the problem. Yet again. I mean, he's
13 supposed to have --

14 SPECIAL MASTER VANASKIE: Yeah, I ruled on this. I
15 ruled on this.

16 Where does that take us to?

17 MR. RAE: We're going to skip ahead another 100 pages
18 now.

19 So our next objection is page 690, lines 15 to 18 and
20 22 to 23.

21 And there's -- we have kind of form and outside the
22 scope objections here which I think are appropriate, but the
23 core of all of our objections, including the 403 and the 701
24 objection here, is that Dr. Jaiswal is being asked to
25 speculate about customer states of mind. And that wouldn't

1 even be an appropriate topic for expert testimony, and it's
2 certainly not an appropriate topic for Dr. Jaiswal to be asked
3 to speculate on.

4 MR. NIGH: Your Honor, the question is, "It's not
5 unreasonable for a customer to expect that their drug is safe,
6 effective, and free of contamination?"

7 And he responds, "Yeah, it's not unreasonable."

8 So he -- again, he's offered up as the person in
9 charge of quality and safety. And the other thing is, like we
10 have gone into all these different warranties. And there are
11 warranties made from Torrent even on their website about their
12 quality of drugs. And that website is clearly there for a
13 reason. Customers can see their website information. They
14 can see information numerous ways.

15 So for us to be able to ask the head of quality and
16 safety, is it unreasonable for customers to expect this, and
17 he says yeah, it's not unreasonable, that's relevant. Highly
18 relevant.

19 SPECIAL MASTER VANASKIE: Yeah, I think this is a
20 proper examination and would overrule the objection.

21 Where are we up to now?

22 MR. RAE: Page 739, line 22 to 24, and then the
23 answer is at page 740, line 3.

24 MR. NIGH: Just to be clear, there was a counter,
25 734:21 to 735:3, we didn't have an objection.

1 SPECIAL MASTER VANASKIE: Okay.

2 MR. NIGH: So that led us to - the next objection is
3 740, line 3.

4 SPECIAL MASTER VANASKIE: So is it an objection to
5 the question whether Torrent has the final say of approval or
6 rejection of components of the valsartan drug pill?

7 MR. RAE: So that's the question that we're objecting
8 to.

9 The basis of the objection is a mix of this is a
10 mischaracterization of the documents and the regulations that
11 Dr. Jaiswal is being presented with.

12 And the broader objection here is -- and the
13 reason -- the basis of our 403 objection is the questions here
14 are about regulations that relate to a drug manufacturer's
15 management of contractors. And plaintiffs want to ask Torrent
16 about those regulations to imply that Torrent should have been
17 applying those regulatory standards to ZHP.

18 There are different FDA regulations that govern the
19 relationship between a drug -- a finished dose manufacturer
20 and suppliers of components, which is the relationship between
21 Torrent and ZHP. These are simply the wrong regulations.

22 And so this entire line of questioning is unduly
23 prejudicial, because ZHP is not a contractor in the sense that
24 the regulations speak of. And the witness even addresses this
25 in his answers. ZHP is a supplier. And the regulations as to

1 suppliers are different from the regulations that relate to
2 contractors. And we shouldn't be presenting confusing
3 testimony to the jury that implies that they should be
4 considering the regulations that relate to the management of
5 contractors.

6 And just to explain that a little bit, this is kind
7 of the difference between stepping out of the pharmaceutical
8 context, say, like a cell phone manufacturer who hires someone
9 else to put all the pieces together and make a finished cell
10 phone and then ships that cell phone under their name versus
11 buying the screen from one place and the modem from another
12 place and then combining those pieces together themselves at
13 the end.

14 And the regulations for those two pieces in the
15 pharmaceutical industry are different. If you hire someone to
16 do the finished dose assembly yourself, that's one set of
17 regulations. And if you buy components, the regulations and
18 the responsibilities are different for the oversight of
19 suppliers.

20 SPECIAL MASTER VANASKIE: Daniel?

21 MR. NIGH: Judge, this is spot on. And that might be
22 their theory. They're happy to present it when their time
23 comes. But to try to inject that as to why this information
24 should be overruled or sustained, I mean, part 211, the title
25 is: Current Good Manufacturing Practice for Finished Dose

1 Manufacturers. Torrent is a finished dose manufacturer.

2 And then when you read below that: There shall be a
3 quality control unit that shall have the responsibility and
4 authority to approve or reject all components of drug product
5 containers.

6 So they have that. And then "Torrent has the final
7 say of approval or rejection of components of the valsartan
8 drug pill." It makes it even more clear.

9 And the witness responds, "Right." And the witness
10 is here testifying in a 30(b) (6) capacity at this point.

11 So I just -- I can't see any way that this isn't
12 admissible. The rest of that statement really didn't make any
13 sense to me, but this is spot on in terms of, you know, what
14 would be relevant. And our experts don't look at this the
15 same way, obviously, as the way their experts do.

16 MR. RAE: And to be clear, I think Mr. Nigh actually
17 made a good point there, and I'm going to withdraw our
18 objection to 739:22 to 743, because I think he is right that
19 that question relates to components of drug product containers
20 and is a reasonable question.

21 But then if you look at 740 -- you don't need to go
22 to the document itself because they read it into the record
23 here. 740:5 through 15 is clear that this shifts to "the
24 quality control unit shall be responsible for approving," and
25 then he skips down a little bit, "for approving or rejecting

1 drug products manufactured, processed, packaged, or held under
2 contract by another company."

3 And the objections that we're going to have on page
4 741 and 745 relate to questioning about that.

5 And I have kind of gotten a little bit ahead of
6 myself, but my explanation of the difference between
7 contractors and suppliers applies to those later objections.

8 But we're withdrawing the objection for the testimony
9 on 739:22 to 740:3.

10 MR. NIGH: Okay. I'm sorry, but I couldn't follow.
11 I just know that the next statement -- if we're moving on from
12 740, line 3, the next statement is 740:22 to 741:12. And
13 there's an objection, it looks like, to 741, lines 6 to 12.

14 Is that the next one you're on?

15 MR. RAE: Correct. And the answer from 15 to 24 on
16 page 741 as well.

17 This is exactly what I was talking about. The
18 question before that is, "Do you understand that Torrent is
19 required to accept or reject drug products...processed or held
20 under contract by another company?"

21 And Dr. Jaiswal clarifies, "Yeah, if we give like a
22 portion of our activity as a -- to the contractor to do that,
23 it's it is a contracted out activity."

24 And there's then a question that follows that that
25 kind of proceeds from the premise that ZHP was a contractor,

1 that this was a contracted out activity. But ZHP is not a
2 contractor, ZHP is a supplier.

3 SPECIAL MASTER VANASKIE: So you're objecting to that
4 question on page 741, line 6, and to the answer that starts on
5 line 15 of page 741?

6 MR. RAE: Right. Yes, Your Honor. And I think
7 Dr. Jaiswal answers these questions accurately, but the line
8 of questioning is going to be confusing and misleading to the
9 jury. It's going to involve this big detour into the
10 distinction between contractors and suppliers, that there's
11 really just no reason to be getting into in this case.

12 And Judge Bumb has expressed concern about making
13 sure that we're streamlining the presentation of evidence for
14 trial, making sure that we're not presenting confusing
15 information to the jury. And really this objection is about
16 making sure that we're not confusing the jury, that we're not
17 wasting time and that we're not going down detours that aren't
18 relevant to the issues in this case.

19 MR. NIGH: Judge, I'm reading 741:6 to 741:24, and I
20 just don't see how it's objectionable. If we're reading it,
21 we're not even talking about a document at this point. We're
22 just talking about, you understand that means that it's a CGMP
23 violation for a manufacturer like Torrent to contract out
24 prescription drug manufacturing without sufficiently ensuring
25 continuing quality of the drug and the subcontractors it

1 relies on.

2 And then we're going to see 15 to 24, and it's just
3 he gives his answer to that.

4 MR. RAE: Your Honor, the problem here is that
5 Torrent didn't contract out prescription drug manufacturing.
6 Torrent manufactured the finished dose products in Torrent's
7 own Indrad facility.

8 And so the entire line of questioning is confusing
9 because the jury is just going to be confused, why is a
10 Torrent witness getting asked about contracting out
11 prescription drug manufacturing and the CGMP requirements that
12 go with that when Torrent didn't do that.

13 SPECIAL MASTER VANASKIE: Yeah. I will sustain the
14 objection.

15 MR. RAE: Thank you, Your Honor.

16 SPECIAL MASTER VANASKIE: What's next?

17 MR. RAE: Next is we have an objection at 745, lines
18 2 to 4 and 7 to 12.

19 And I think prior rulings from Your Honor are
20 probably going to lead to overruling this objection, so --

21 SPECIAL MASTER VANASKIE: Yes. Looking at the line
22 of questioning, I think the objection is not well taken and is
23 overruled.

24 MR. RAE: And then we're going to be on to Volume 3
25 at this point.

1 And for the record, Your Honor, I think that all of
2 the rest of our objections are going to -- actually, I'm
3 sorry. I'm getting ahead of myself. We're not quite to that
4 point yet.

5 SPECIAL MASTER VANASKIE: All right. So what's our
6 next objection? Go ahead.

7 MR. NIGH: I think what he was going to say is when
8 we get to 935, I think we have a lot of just reserving. I
9 struck a lot of the testimony too.

10 So we only have about 100 pages to go.

11 The next objection is page 831, line 14 to 832, line
12 8, I believe.

13 MR. RAE: Right.

14 MR. NIGH: And it's specifically for 832:6 to 8.

15 If I can, I'm going to pull up the day 3 transcript
16 here.

17 MR. RAE: Your Honor, we have a number of objections
18 here that are going to span kind of the testimony beginning on
19 831. Our objections running through I believe 87 -- the
20 testimony on page 877, this may all apply to that. And we
21 have kind of Torrent-specific objections here, but I think
22 there's a bigger picture issue, which is the defendant moved
23 in limine to exclude regulatory inspection reports and other
24 investigation reports that don't relate to valsartan as a drug
25 product itself.

1 And as the testimony establishes here, this is an EIR
2 from -- it's another ZHP EIR. So I think Your Honor's prior
3 rulings about the appropriateness of examining a Torrent
4 witness on that document, while we disagree with them, would
5 likely apply to the majority of our objections here. And it
6 may be best if we're in that space, for us to go back and kind
7 of try to hash that out with plaintiffs to see if there's any
8 objections in this category that would need further resolution
9 from you versus working through them here.

10 There's a bigger issue, which is that this EIR report
11 relates to the FDA's inspection of ZHP's manufacture of a
12 different drug substance -- I think it's pronounced
13 tadalafil -- and that Judge Bumb has ruled that inspection and
14 investigation reports and consultant materials and other
15 things like that in response to joint defendants' motion in
16 limine 2 do not come into this case unless they either relate
17 to valsartan or plaintiffs are able to -- I think she also
18 ruled could clearly connect the dots back to there being some
19 connectivity to valsartan.

20 And I think our position would be -- and I suspect
21 that counsel for ZHP would agree with us on this, although I
22 haven't discussed it with Ms. Rose -- is that this testimony
23 should all be excluded under that motion in limine because it
24 all relates to a report that ties to ZHP's manufacture of a
25 different API.

1 And I recognize that that may be an issue that's best
2 suited for either of the parties to work amongst themselves to
3 resolve or go back to Judge Bumb for clarification on the
4 scope of her motion in limine ruling, although our position
5 would be that her motion in limine ruling is incredibly clear
6 on this issue.

7 MR. NIGH: Jacob, I just want to, what lines -- where
8 do you think this starts and ends for your objections on what
9 you're speaking to?

10 MR. RAE: I think this -- the issue that I'm
11 describing with respect to the EIR relates to the questioning
12 on the May 2017 EIR, the ZHP EIR.

13 SPECIAL MASTER VANASKIE: So can you give us a page
14 and line?

15 MR. NIGH: Yes. And how far, where does this end?

16 MR. RAE: This begins on -- I think it begins really
17 on probably page 830 or 831. There's a discussion of kind of
18 a ZHP document. And then our objections that we had
19 originally framed on this begin on page 832, line 6.

20 MR. NIGH: And where does it end, do you know?

21 MR. RAE: I believe that this issue would run
22 through -- at a certain point, this questioning transitions to
23 the 483 warning letter on the same issue.

24 I think we would take the same position, that the
25 FDA's 483 warning letter, our kind of 403 and 602 objections

1 are going to become a little bit different there, but Judge
2 Vanaskie has already addressed those. So, again, I think we
3 would be able to work out a stipulation as to the application
4 of those prior rulings there.

5 But it would run through, I believe, 877:6, where
6 there's kind of ongoing discussion of both the EIR and FDA 483
7 warning letter related to this inspection that was to ZHP's
8 production of tadalafil.

9 MR. NIGH: Your Honor, it may be -- I think that this
10 range may be best if we just go back and meet and confer on
11 it.

12 I was -- as I'm looking at this, I'm under the
13 impression this is the EIR inspection report that has to do
14 specifically with valsartan, so -- but what's being conveyed
15 here does not sound like that, and so I think it might be best
16 for us to meet and confer and see where the disconnect is. It
17 could be on our side, it could be on Torrent's side.

18 I mean, I just -- I think if we go back and look at
19 it, we may reach an agreement here based on the rulings you've
20 given thus far.

21 SPECIAL MASTER VANASKIE: All right. Why don't you
22 meet and confer taking into account rulings made thus far.

23 Can you get me a letter report by Monday of next week
24 where this stands?

25 MR. NIGH: I believe so. We can probably even get on

1 the next call and tell you, you know, where this stands.

2 SPECIAL MASTER VANASKIE: Okay. That would be
3 helpful.

4 MR. RAE: I would agree with that.

5 And again, just to -- I think that we also have a few
6 counter-objections in there, so there may be kind of a need to
7 discuss those, although maybe the prior guidance from Your
8 Honor would also address our counter-designations to the
9 extent this does come in.

10 SPECIAL MASTER VANASKIE: Okay. So where does that
11 take us to now?

12 MR. RAE: So we are now -- we're now at 896, line 16.

13 SPECIAL MASTER VANASKIE: All right. Let's take a
14 15-minute break at this time.

15 MR. RAE: Okay. Thank you, Your Honor.

16 SPECIAL MASTER VANASKIE: Thanks.

17 MR. NIGH: Thank you.

18 (Recess at 3:01 p.m. until 3:17 p.m.)

19 SPECIAL MASTER VANASKIE: All right. So where are we
20 picking up, Jacob?

21 MR. RAE: I think we are picking up at 896:16 to 18.

22 SPECIAL MASTER VANASKIE: Give me a second here.

23 MR. NIGH: And, Judge, if I may, I think I have a way
24 to clear this up that may be amenable to both sides.

25 I would agree that the "I just want to make sure that

1 this is absolutely clear for the jury" is just attorney
2 commentary, so that would be stricken.

3 | SPECIAL MASTER VANASKIE: Okay.

4 MR. NIGH: Which would just be 16, 17 and -- for that
5 one.

6 And then the next one is 897:11 and 12.

7 SPECIAL MASTER VANASKIE: Hold on a second. Let me
8 catch up to you.

9 | 896, you would leave in 16 to 18?

10 MR. NIGH: We would strike just 16 and the word
11 "quick" on 17 and strike "I just want to make sure that t
12 is absolutely clear for the jury."

13 SPECIAL MASTER VANASKIE: Oh, I got you. I got you.
14 Okay.

15 MR. RAE: Agreed. I was going to clarify that that
16 was really the heart of our objection, so I think we're on the
17 exact same page there.

18 MR. NIGH: Uh-huh.

19 | SPECIAL MASTER VANASKIE: Good.

20 MR. NIGH: And then on 897:11 and 12, the only
21 thing we need -- it's actually 897:11, 12 and the one number
22 on 13, "It should be marked as Torrent 79. That's LP 1218,"
23 that just helps keep track of the documentation. So it lays
24 the foundation of this document.

25 | SPECIAL MASTER VANASKIE: Okay. All right.

1 MR. RAE: I'm happy with that compromise. We can...

2 SPECIAL MASTER VANASKIE: What else do we have?

3 MR. RAE: The next objection is at 915:6 to 15.

4 Sorry. It's actually 915 -- our objection is only at
5 915:13 to 15. I misspoke. And then we also have an objection
6 to lines 19 and 20 on that page.

7 And this is -- from our perspective, this is just an
8 issue of this is attorney commentary. There's no -- it's --
9 you have to go to page 917 before you get to the next question
10 and answer. And there's no answer designated to either of
11 these questions.

12 MR. NIGH: And, Judge, I haven't been able to let
13 Jacob know this, but 915 all the way to -- it looks like it
14 goes all the way to 932. You know, we're touching back on
15 this July ZHP 2018 report. And we may very well be amenable
16 to withdrawing this whole section based on what's already come
17 in, you know, as long as the counters are also withdrawn.

18 MR. RAE: Your Honor, that's -- I'm hearing that for
19 the first time. We're going to have to kind of consider that,
20 although I think this also is going to be tied up in the
21 motion in limine issue that we may kind of either need to
22 resolve or seek clarification from Judge Bumb on. So I think
23 that that probably is not something that we should be
24 addressing today in light of what Mr. Nigh just said.

25 MR. NIGH: Yeah. And to go --

1 SPECIAL MASTER VANASKIE: I just don't want there to
2 be unaddressed loose ends.

3 So what I'd ask you to do is to get a letter report
4 to me by Monday of next week on this and the other matters we
5 talked about earlier.

6 It looks to me like you'll resolve this. I just
7 don't want it to fall through the cracks.

8 MR. NIGH: And, Your Honor, if we're able to get it
9 on the record at one of the next meetings, that would be
10 Thursday or Friday, that would be okay too. Right?

11 SPECIAL MASTER VANASKIE: Yes. Absolutely. I should
12 say by Monday of next week. So if you can get it on the
13 record before then, Thursday or Friday of this week, that
14 would be great.

15 MR. NIGH: So I do think they're two different
16 issues, 915 and 932. Everything that we designated there, we
17 may just see as somewhat akin to something we've already
18 designated, so we would take that out if that includes the
19 counters.

20 And then 935 to 951, we've had some discussion on
21 this already. And I think we both agree that it's better to
22 see how Judge Bumb's rulings come in on, you know, other EIR
23 inspections and things of that nature, specifically how it
24 comes in before we argue 935 to 951.

25 SPECIAL MASTER VANASKIE: All right.

1 MR. RAE: And I agree with the general thrust of what
2 Mr. Nigh said. I think just for the record, our position is
3 that Judge Bumb has already been incredibly clear in ruling
4 that the -- this EIR and kind of other issues as I spoke to
5 earlier are not admissible evidence in this trial, but it
6 sounds like we have a disagreement with plaintiffs about the
7 scope of that motion in limine ruling. And that the right
8 next step is for us and I think probably the defendants
9 collectively to discuss this with the plaintiffs collectively
10 to figure out if we can reach an agreement there or if we need
11 to go back to Judge Bumb on that.

12 SPECIAL MASTER VANASKIE: All right. Very well.

13 MR. RAE: And I think that takes us -- that wraps up
14 Dr. Jaiswal, unless I'm missing something.

15 MR. NIGH: It does.

16 Your Honor might have 952 designations, but we
17 removed everything from 952 forward. So we -- the plaintiffs
18 agreed to strike all the rest of the testimony.

19 SPECIAL MASTER VANASKIE: Yeah. The spreadsheet I
20 have stops at 947.

21 MR. NIGH: Okay. Great.

22 SPECIAL MASTER VANASKIE: All right.

23 MR. NIGH: And that is it for Jaiswal.

24 SPECIAL MASTER VANASKIE: Well, we did Kelly
25 Gegenheimer and Sushil Jaiswal, so that's some progress.

1 What else can we accomplish today?

2 MR. NIGH: That's a lot of progress for us, Your
3 Honor. That's about half of our Torrent-designated testimony.

4 MR. RAE: And I think that's probably material -- my
5 guess is that's materially more than half of the objections
6 and counter-designations, that it's half of the testimony but
7 that it's a bigger chunk of the objections.

8 SPECIAL MASTER VANASKIE: Right.

9 MR. NIGH: Yes.

10 SPECIAL MASTER VANASKIE: You know, I think it would
11 be helpful for me if you would let me know which witnesses and
12 if there's an order that makes sense, witnesses I should
13 prepare for for our next get-together.

14 I have not -- on Gegenheimer and Jaiswal, I had
15 looked at their testimony. I haven't looked at the testimony
16 of the other witnesses. So I'm thinking it might make better
17 sense if you can give me some direction where to focus my
18 attention so Thursday we can hit the ground running, so to
19 speak.

20 As I did with the ZHP witnesses and with some of the
21 witnesses, including witnesses today, I've previewed it and
22 made initial determinations, and I intend to do the same for
23 the remaining witnesses.

24 MR. NIGH: Do we have Thursday and Friday? I just
25 wanted to be clear.

1 SPECIAL MASTER VANASKIE: We have Thursday and
2 Friday.

3 MR. NIGH: So my suggestion might be, you know, we
4 handled so much more of Torrent, and I think Jacob will agree.
5 I think for us that it might make sense for our next ones that
6 we put on the balance of the witnesses on Friday.

7 It sounds like there are a few witnesses that Teva
8 has sent ready to tee up that may be ready on Thursday, and I
9 suspect there are also some ZHP witnesses for Thursday as
10 well.

11 So Thursday is probably Teva/ZHP, and then we come
12 back to Friday on the balance of the Torrent witnesses.

13 SPECIAL MASTER VANASKIE: All right. David, do you
14 agree?

15 MR. STANOCH: That makes sense for me, Your Honor, in
16 terms of Teva for Thursday with at least the two that we --
17 Pan Lin and Vadsola that you have.

18 SPECIAL MASTER VANASKIE: Right.

19 MR. STANOCH: And we're trying to get you on a
20 rolling basis anything else.

21 SPECIAL MASTER VANASKIE: Nina, is that all right
22 with you?

23 MS. ROSE: That's fine, Your Honor. I was just
24 wondering if you had a sense of how much time you had
25 available on Thursday. We will be ready to go. I believe

1 we've already sent you several charts for our witnesses.

2 SPECIAL MASTER VANASKIE: You have.

3 MS. ROSE: But I just want to kind of get a sense for
4 my schedule for other meetings on Thursday how long you would
5 be available.

6 MR. HARKINS: That's the same question for Teva, Your
7 Honor. Victoria unfortunately had to drop, but we're happy to
8 talk scheduling. I do think it would be helpful to know if we
9 think we might get to any witnesses beyond the two that have
10 been submitted already.

11 SPECIAL MASTER VANASKIE: It was scheduled to start
12 at 10:00 a.m. on Thursday, and we'll go till 5:00 if that's
13 all right. And the same thing Friday.

14 I don't have a start time for Friday. We could start
15 at 10:00 a.m. on Friday. We can start earlier if you'd like.

16 MR. NIGHT: And, Your Honor, I think 10:00 a.m. Friday
17 is just fine. I don't mind starting earlier if you want to as
18 well.

19 But I think on Friday, I think at a minimum we should
20 try to tackle Dawn Chitty, who if I were to say the next
21 percentage is probably, you know, like 25 -- like Jaiswal is
22 almost 50 percent of the objections, and Chitty is probably
23 another 25 percent. So that's probably next big chunk.

24 SPECIAL MASTER VANASKIE: Okay.

25 MR. NIGHT: So I think we tee up Chitty as our first

1 one on Friday.

2 Would you agree, Jacob?

3 MR. RAE: I'm happy -- I agree with your
4 representation as to the volume. I think it's probably a
5 little bit less than 25 percent, but I haven't gone back and
6 measured them entirely.

7 And then I'm happy to proceed in the order that you
8 guys think makes sense for working through these. I don't
9 have any real preference on order of witnesses that we
10 discuss.

11 MR. NIGH: Okay.

12 MR. STANOCH: Your Honor, for Thursday, at least as
13 to plaintiffs' designations of Teva, we're happy to start as
14 early as you and Ms. Mitchell would like to start. Any time
15 that day we're good.

16 SPECIAL MASTER VANASKIE: How about 9:30? Let's
17 start at 9:30.

18 MR. HARKINS: Judge, I don't think that will be any
19 issue. I just do want to confirm with Ms. Lockard when she
20 gets back on. We'll certainly send you something, but I think
21 preliminarily that should probably work for us.

22 SPECIAL MASTER VANASKIE: All right. And if she
23 needs to start later, that would be fine as well. All right?

24 I think then we can be concluded for today.

25 Ann Marie, you're going to have a lot of transcribing

1 to do. And thank you for your patience with us today.

2 We'll see you all on Thursday.

3 RESPONSE: Thank you, Your Honor.

4 (Proceedings concluded at 3:30 p.m.)

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6 **FEDERAL OFFICIAL COURT REPORTER'S CERTIFICATE**

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8 I certify that the foregoing is a correct transcript
9 from the record of proceedings in the above-entitled matter.

10

11 /S/ Ann Marie Mitchell 25th day of September, 2024

12 CCR-RDR-RMR-CRR

13 Court Reporter/Transcriber

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